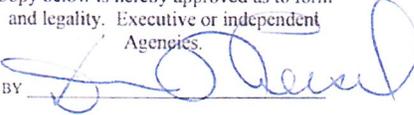






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NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

28 PA. CODE CHAPTERS 1141-1230

MEDICAL MARIJUANA

The Department of Health (Department), proposes to promulgate permanent regulations in 28 Pa. Code Part IXa (pertaining to medical marijuana) by replacing the current temporary regulations at 28 Pa. Code Part IX. The proposed permanent regulations are set forth in Annex A.

**A. PURPOSE OF THE PROPOSED RULEMAKING**

Pursuant to the authority granted to the Department under 35 P.S. § 10231.1107 (relating to temporary regulations), the Department promulgated temporary regulations to facilitate the prompt implementation of the Medical Marijuana Act (35 P.S. §§ 10231.101-10231.2110) (the act). 46 Pa.B. 3254 (June 25, 2016); 46 Pa. B. 6829 (October 29, 2016); 46 Pa. B. 8036 (December 24, 2016); 47 Pa. B. 73 (January 7, 2017); 47 Pa.B. 74 (January 7, 2017); 47 Pa.B. 199 (January 14, 2017); 47 Pa.B. 217 (January 14, 2017); 47 Pa.B. 269 (January 14, 2017); 47 Pa.B. 3096 (June 3, 2017); 47 Pa.B. 6938 (November 11, 2017); 48 Pa.B. 1508 (March 17, 2018). Pursuant to 35 P.S. § 10231.1107, the Department's authority to adopt temporary regulations was to expire May 12, 2018, two years after the effective date of 35 P.S. § 10231.1107. Prior to the expiration of its authority to adopt temporary regulations, the Department promulgated a second set of temporary regulations, with an expiration date of May 12, 2020. 48 Pa.B. 2767 (May 12, 2018); 48 Pa.B. 2793 (May 12, 2018); 48 Pa.B. 2801 (May 12, 2018); 48 Pa.B. 2806 (May 12, 2018); 48 Pa.B. 2810 (May 12, 2018); 48 Pa.B. 2814 (May 12, 2018); 48 Pa.B. 2767 (May 12, 2018).

On June 22, 2018, the General Assembly amended Chapter 20 of the act and provided the Department with authority to issue new temporary regulations to implement the revised Chapter 20. 35 P.S. §§ 10231.2000-10231.2004. Pursuant to Section 2004 of the act, the

Department's authority to issue Chapter 20 temporary regulations was to expire two years after initial publication of the amended Chapter 20 temporary regulations. The Department rescinded the initial Chapter 20 temporary regulations on July 28, 2018, 48 Pa. B. 4493 (July 28, 2018), and promulgated revised Chapter 20 temporary regulations on August 18, 2018, and on December 22, 2018. 48 Pa. B. 5072 (August 18, 2018); 48 Pa. B. 7778 (December 22, 2018).

This proposed rulemaking is intended to revise and replace the current temporary regulations found in Part IX of Title 28 (pertaining to medical marijuana) to implement permanent regulations governing the medical marijuana program in a new Part IXa of Title 28. These proposed regulations will further the purpose of the act by providing access to medical marijuana for patients with serious medical conditions; ensuring a safe and effective method of distribution; and promoting high-quality research into the efficacy of medical marijuana.

As a prefatory note, the current temporary regulations include Chapter 1131 (relating to safe harbor letter). Chapter 1131 has expired and will be reserved.

## **B. REQUIREMENTS OF THE REGULATION**

### **CHAPTER 1141a. GENERAL PROVISIONS**

This proposed chapter replaces the current Chapter 1141 (relating to general provisions -- temporary regulations). Proposed new sections and amendments to sections of the current temporary regulations are discussed more fully below.

**Section 1141a.21. Definitions.**

This proposed section replaces the current Section 1141.21 (relating to definitions). In addition to including all definitions currently in Section 1141.21, this proposed section consolidates all definitions under this proposed part in this section instead of defining the terms separately in each chapter.

Beyond consolidating terms that are defined elsewhere, this proposed section revises the definitions of the following terms defined in the current temporary regulations. The definition of “ACRC” was revised to mirror the definition of “Academic Clinical Research Center” in the act and the definition of “certified ACRC” was removed as redundant. The definition of “added substance” is revised by replacing “and” with “or” to clarify that either an “additional ingredient” or “any substance” constitutes an “added substance.” Additionally, “any substances” is revised to the singular “any substance.” The definition of “applicant” is revised to include persons who apply to become an approved laboratory, an ACRC, or a clinical registrant and to move subsections (ii) and (iii) from subsection (C) to subsection (B), as initial placement in subsection (C) was in error.

The definition of “CBD” is revised to add the substance’s Chemical Abstracts Service (CAS) number in order to conform to scientific standards of substance identification. The definition of “clinical registrant” is revised to add proposed subsection (iii) because the unnecessary definition of “approved clinical registrant” was removed. The definition of “continuing care” is revised to mirror the definition in the act by adding “including an in-person consultation with the patient” to the end. The definition of “controlling interest” is

changed to mirror the definition in the act by changing “company” to “entity” in subsection (i).

The definition of “laboratory applicant” is removed as the definition of “applicant” is revised to include persons who apply to become an approved laboratory. The definition of “marijuana” is revised to exclude synthetic marijuana. The definition of “medical marijuana organization” is revised to remove the exclusion of a clinical registrant, to comport with section 2002(b)(5) of the act. The definition of “municipality” is revised to add “county” and “or any similar general purpose unit of government which shall hereafter be created by the General Assembly.” The definition of “permit” is revised by changing “applicant” to “medical marijuana organization” to reflect the definition of “permit” in the act.

The definition of “serious medical condition” is revised to add “anxiety disorders,” “Tourette’s Syndrome” and “any other condition recommended by the Medical Marijuana Advisory Board and approved by the Secretary. These revisions follow from Section 1202 of the act, which charged the Medical Marijuana Advisory Board (Board) with issuing a final report making various recommendations. 35 P.S. § 10231.1201(j). The Board issued its final report and, in accordance with 35 P.S. § 10231.1201(j)(6), adopted the report at a public meeting on April 9, 2018. The Board’s final report recommended that a process be established for a subcommittee of the Board to review and approve additional serious medical conditions on a continuous basis; the Secretary approved this recommendation. 48

Pa.B. 2898. The definition of “THC” is revised to clarify that the term refers to “Delta-9” tetrahydrocannabinol.

Further, this proposed section defines these previously undefined terms: “added substance,” “CAS number,” “CBC,” “CBDA,” “CBDV,” “CBG,” “CBN,” “cannabinoids,” “D8,” “medical marijuana extract,” “professional disciplinary action,” “THCA,” “THCV,” and “terpenes.” The addition of these terms and corresponding definitions is meant to provide greater clarity in identifying the chemical compounds used in medical marijuana products.

Finally, due to revising the definition of “applicant,” the Department proposes to remove the definitions of “approved clinical registrant” and “certified ACRC” as unnecessary. To correspond to these changes, the Department proposes to revise the definitions of “IRB,” “RAC,” and “Research contract” to remove the reference to “certified” ACRC.

**Section 1141a.22. Records subject to disclosure; confidentiality.**

This proposed section replaces the current Section 1141.22 (relating to records subject to disclosure; confidentiality). The Department proposes to revise subsection (b) and to add subsections (f) and (g), as detailed below.

*Subsection (a).*

This proposed subsection mirrors the current subsection (a). This proposed subsection lists what records are public records subject to disclosure under the Right-to-Know Law. 65 P.S. §§ 67.101—67.3104 (RTKL).

*Subsection (b).*

This proposed subsection lists what information is considered confidential and not subject to the RTKL. The Department proposes to revise paragraph (11) of this subsection to replace the phrase “The names and any other information relating to” with “Any information that would identify.” This amendment is being proposed to clarify any ambiguity relating to the confidentiality of individuals who review permit applications to protect the identities of, and any other information pertaining to, those individuals.

Section 306 of the Right to Know Law (RTKL) provides that “[n]othing in [the RTKL] shall supersede or modify the public or nonpublic nature of a record or document established in . . . regulation.” 65 P.S. § 67.306. In order to score the permit applications, the Department collaborated with a multitude of Commonwealth agencies. In an effort to dissuade applicants from attempting to exert any improper influence—an unfortunate but realistic concern when introducing a new billion-dollar industry—the Department protected the confidentiality of individuals who scored the applications by promulgating the temporary regulation, and the Department has determined that such protection remains necessary to carry out the provisions of the act.

*Subsection (c).*

This proposed subsection mirrors the current subsection (c). This proposed subsection provides that applicants are responsible for marking confidential proprietary information contained in their applications prior to submission.

*Subsection (d).*

This proposed subsection mirrors the current subsection (d). This proposed subsection provides that an applicant’s failure to redact confidential proprietary information contained

in the application will result in the disclosure of that information if requested under the RTKL.

*Subsection (e).*

This proposed subsection mirrors the current subsection (e), except for adding language to clarify that an applicant is responsible for defending only those redactions it makes to protect its confidential proprietary or trade secret information. This proposed subsection provides that applicants are responsible for defending such redactions in their applications in any administrative or court hearing and that unsuccessful defense thereof may result in full disclosure of the application in unredacted form.

*Subsection (f).*

This proposed subsection is new and provides that the Department may release de-identified data for research purposes that are subject to approval and oversight by the Department and an IRB. The nascent nature of the medical marijuana program requires not only constant review of the efficacy of the program for its current purposes, but also research into potential areas of improvement. The addition of this proposed new subsection serves to effectuate those goals.

*Subsection (g).*

This proposed subsection is new and permits the Department to collaborate with other Commonwealth agencies for purposes of investigating and enforcing violations of the act and regulations. This is necessary because other agencies have regulatory authority outside of the act, such as the Department of State in the licensing and professional conduct of practitioners, and collaboration is required by the act.

**Section 1141a.23.                    Limitation on number of permits.**

This proposed section mirrors the current Section 1141.23 (relating to limitation on number of permits), except for changing “Notwithstanding” to “Except as provided in” as the introduction to the section and revising incorrect citations in subsection (3). This proposed section sets the limits on the amount of grower/processor and dispensary permits the Department may issue and the limit of permits that may be received by one person.

**Section 1141a.24.                    Medical marijuana regions.**

This proposed section mirrors the current Section 1141.24 (relating to medical marijuana regions). This proposed section outlines the geographic areas contained in each of the six medical marijuana regions in this Commonwealth. Further, this proposed section provides factors the Department will consider when issuing a permit and that the Department may change the number or boundaries of the regions every two years.

**Section 1141a.25.                    General requirements for permits.**

This proposed section mirrors the current Section 1141.25 (relating to general requirements for permits). This proposed section outlines the general guidelines and prohibitions with respect to permits.

**Section 1141a.26.                    Privilege and nontransferability.**

This proposed section mirrors the current Section 1141.26 (relating to privilege and nontransferability). This proposed section provides that the issuance or renewal of a permit is a revocable privilege, and that permits are nontransferable.

**Section 1141a.27. General requirements for application.**

This proposed section replaces the current Section 1141.27 (relating to general requirements for application). The Department proposes to revise subsections (a), (c), and (d), as detailed below.

*Subsection (a).*

This proposed subsection lists the types of applications to be submitted to the Department. The Department proposes to revise subsections (a)(3), (a)(4), and (a)(5) by removing the phrase “as authorized by a permit.” This phrase is unnecessary because the definitions of “medical marijuana organization” and “facility” make clear that a permit has been issued. The Department proposes to additionally revise subsection (a)(4), which currently provides for “[a]n application for approval of a change of location of a facility.” This proposed rulemaking revises subsection (a)(4) to add that an application to change location may be submitted only for an “operational” facility. This revision clarifies that the regulation was never intended to apply to non-operational facilities, as permit applications are scored based upon the location provided within the application itself, and a successful applicant’s attempt to relocate before operationalizing the location provided in the application undercuts the application and scoring processes. Beyond these revisions, this proposed subsection mirrors the current subsection (a).

*Subsection (b).*

This proposed subsection mirrors the current subsection (b). This proposed subsection provides that, by submitting an application, an applicant consents to any necessary investigations to ensure the applicant’s ability to meet the requirements under the act.

*Subsection (c).*

This proposed section mirrors the current subsection (c), except for changing the citation in proposed subsection (c)(1) to refer to this new proposed chapter and adding “for an initial permit or for a permit renewal” after “application” to clarify that this provision applies to medical marijuana permit applications. This proposed subsection lists the information that is required with the submission of an application. If this required information is not included, the application will be rejected as incomplete.

*Subsection (d).*

This proposed subsection provides that an incomplete application will be rejected. This proposed subsection revises the language in the current subsection (d), which provides that “[a]n application that is rejected by the Department as incomplete will be returned to the applicant without further consideration by the Department and the initial permit fee will be refunded.” This proposed subsection removes the requirement on the Department to return an incomplete application, making for a more efficient and cost-effective operation. Additionally, the language regarding refunding the initial permit fee has been relocated to proposed subsections 1141a.28(a)(2) and (b)(2). This proposed subsection also adds “for an initial permit” after “application” to clarify that this provision applies only to initial permit applications.

**Section 1141a.28. Fees.**

This proposed section replaces the current Section 1141.28 (relating to fees), with revisions to subsections (a), (b), and (c), as detailed below.

*Subsection (a).*

This proposed subsection provides the fee amounts for initial and renewal grower/processor permits, and to whom initial permit fee refunds will be refunded. The current subsection (a) provides that the fee for these permits must be paid by “certified check or money order.” This proposed subsection expands the acceptable forms of payment to include cashier’s checks. This revision provides applicants greater flexibility in their choice of payment. Proposed subsection (a)(2) is revised to clarify that the permit fee will be refunded if the application is rejected, as well as if the permit is not granted. Beyond these revisions, this proposed subsection mirrors the current subsection (a).

*Subsection (b).*

This proposed subsection provides the fee amounts for initial and renewal dispensary permits, and to whom initial permit fees will be refunded. The current subsection (b) provides that the fee for these permits must be paid by “certified check or money order.” This proposed subsection will expand the acceptable forms of payment to include cashier’s checks. This revision will provide applicants greater flexibility in their choice of payment. Proposed subsection (b)(1) is revised to match the language in subsection (a)(1) and proposed subsection (b)(2) is revised to clarify that the permit fee will be refunded if the application is rejected, as well as if the permit is not granted. Beyond these revisions, this proposed subsection mirrors the current subsection (b).

*Subsection (c).*

This proposed subsection provides that a medical marijuana organization shall pay a \$250 fee for: (1) “an application for approval of a change in ownership,” (2) an application for approval of a change of location of a facility, and (3) an application for approval of

alteration of a facility. The proposed subsection makes three changes to the current subsection. First, the Department proposes to add “cashier’s check” as an acceptable form of payment in subsection (c), consistent with the revisions to proposed subsections (a) and (b). Second, the Department proposes to remove the unnecessary phrase “authorized by permit” in current subsections (a)(2) and (a)(3). Finally, the Department proposes to revise the current subsection (c)(2) to add the word “operational” before “facility,” consistent with the revision to subsection 1141a.27(a)(4) (relating to general requirements for application) to provide that a permittee must operationalize a facility at the location included in its application before it may attempt to move location.

**Section 1141a.29. Initial permit application.**

This proposed section replaces the current Section 1141.29 (relating to initial permit application). While this proposed section largely tracks the current Section 1141.29, this proposed section includes amendments to subsections (a) and (b), as detailed below.

*Subsection (a).*

This proposed subsection mirrors the current subsection (a), except for changing the citation in proposed subsection (a)(2) to refer to this new proposed chapter. This proposed subsection provides that the Department will publish notice of initial application availability in the *Pennsylvania Bulletin*; that the applicant may only use the application form prescribed by the Department; that applicants are required to redact their applications; and that untimely submissions will not be accepted.

*Subsection (b).*

This proposed subsection requires certain information from an applicant in addition to that required by proposed section 1141a.27 (relating to general requirements for application). Beyond the revisions detailed below, proposed subsection (b) mirrors the current regulatory provisions.

This proposed subsection revises the citations in proposed subsections (b), (b)(6)(iii), (b)(9)(iv), (b)(12)(xii), and (b)(13) to refer to this new proposed chapter.

Further, this proposed subsection revises the language of the current subsection (b)(6)(iv) by adding “financial backer” to the introductory phrase for consistency throughout the subsection. Currently, subsection (b)(6)(iv)(B) requires an affidavit from each principal or operator of the applicant setting forth “[w]hether the principal, operator or financial backer has been convicted of a criminal offense graded higher than a summary offense.” This proposed subsection revises this language to reflect that applicants must disclose if they had previously been convicted of a criminal offense graded higher than a summary offense “in this Commonwealth or the lowest-graded criminal offense in another State or country.” This revision clarifies standards for reporting criminal convictions to the Department in light of the differing gradations of crimes in other states and countries. Proposed subsection (b)(6)(iv) also adds subsections (C) and (D), which are reworded and relocated from current subsections 1141.29(b)(9)(vi) and (vii), because those subsections are more appropriately located in the section of the application requiring disclosures via affidavit.

Last, this proposed subsection revises the language in current subsection (b)(9)(v). Currently, subsection (b)(9) outlines the types of evidence that would factor into the Department's determination of an applicant's ability to establish and operate a facility. Subsection (v) was deleted as duplicative of background check requirements in subsection (b)(6). Subsections (vi) and (vii) are moved as reworded to 1141a.29(b)(6)(iv) because they are more appropriately located in the section of the application requiring disclosures via affidavit.

Current subsection (b)(9)(v) provides that the Department will factor in evidence of criminal actions graded higher than a summary offense under the laws of (1) Pennsylvania, (2) any other state, (3) the United States, or (4) a military, territorial, or tribal authority. Consistent with amendments in proposed subsection (b)(6)(iv)(B), this proposed revision requires that the criminal conviction must be graded higher than a summary offense "in this Commonwealth or the lowest-graded criminal offense in another State or country." This proposed change provides the same clarity to applicants as the proposed change to subsection (b)(6)(iv)(B).

*Subsection (c).*

This proposed subsection mirrors the current subsection (c). It provides that if the Department determines that an initial permit application is complete but lacking information, the Department may, but is not obligated to, request the additional information from the applicant. Once contacted, an applicant has 30 days to provide the additional documentation.

*Subsection (d).*

This proposed subsection mirrors the current subsection (d). It provides that the Department may, in its discretion, extend the deadline in proposed subsection (c) for up to an additional 15 days.

*Subsection (e).*

This proposed subsection mirrors the current subsection (e). It specifies the Department's investigatory authority to inspect different facets of an applicant's site and compliance with the act and regulations, in addition to potentially interviewing individuals affiliated with the applicant's facility.

**Section 1141a.30. Capital requirements.**

This proposed section mirrors the current Section 1141.30 (relating to capital requirements). This proposed section provides that a medical marijuana organization applicant must provide an affidavit, confirming that the applicant has the necessary amount of funds on deposit with one or more financial institutions.

**Section 1141a.31. Background checks.**

This proposed section replaces the current Section 1141.31 (relating to background checks). While this proposed section largely tracks the current Section 1141.31, this proposed section includes revisions to subsections (a) and (c), as detailed below.

*Subsection (a).*

This proposed subsection mirrors the provisions of the current subsection (a), except for changing the citation to refer to this new proposed chapter. This proposed subsection provides the way the Department will conduct criminal background checks on applicants and their affiliates.

*Subsection (b).*

This proposed subsection mirrors the current subsection (b). This proposed subsection provides that the Department will only use the criminal background check for the limited purpose of determining character, fitness, and suitability to serve in the individual's designated capacity.

*Subsection (c).*

This proposed subsection exempts from its provisions an owner of a publicly traded company, except in certain circumstances. The current subsection (c) provides that Section 1141.31 does not apply to an owner of securities in a publicly traded company "if the Department determines that the owner is not substantially involved in the activities of the medical marijuana organization." The Department proposes to revise this subsection to omit the above-quoted language. In making this revision, the Department proposes that proposed section 1141a.31 will not apply to an owner of securities in a publicly traded company "unless the owner holds 5% or more of the company's securities or the owner has voting rights to elect or appoint one or more members of the board of directors or other governing board." This proposed change provides clarity with respect to who is exempt from background checks.

**Section 1141a.32. Diversity goals.**

This proposed section mirrors the current Section 1141.32 (relating to diversity goals), except for changing the citation in proposed subsection (g) to refer to this new proposed chapter. This proposed section outlines the Department's intent that medical marijuana organizations establish practices and procedures for promoting and ensuring diversity. Under this proposed section, applicants are required to include in their application a diversity plan, including contracts with diverse vendors, efforts to recruit diverse participants, and the diversity in the applicant's workforce. The Department will review the diversity plans submitted by applicants for viability. Applicants must also include in the renewal applications information of their efforts to meet their diversity goals and the effectiveness of its diversity plan.

**Section 1141a.33. Review of initial permit applications.**

This proposed section mirrors the current Section 1141.33 (relating to review of initial permit applications), except for changing the citation in proposed subsection (a) to refer to this new proposed chapter. This proposed section provides that the Department will review initial permit applications in accordance with Section 603(a.1) of the act and the factors in proposed subsection 1141a.24(b) (relating to medical marijuana regions). Further, the Department will publish the number of permits and the locations thereof in the *Pennsylvania Bulletin*.

**Section 1141a.34. Denial of permit.**

This proposed section mirrors the current Section 1141.34 (relating to denial of permit), except for changing the citations in proposed subsections (3) and (8) to refer to this new proposed chapter. This proposed section delineates the grounds upon which the Department will deny the issuance of a permit to an applicant.

**Section 1141a.35. Notice of denial.**

This proposed section mirrors the current Section 1141.35 (relating to notice of denial), except for amending a citation to refer to the new proposed Chapter 1230a (relating to practice and procedure). Under this proposed section, the Department will provide written notice of denial to an applicant, and the applicant may then appeal a notice of denial.

**Section 1141a.36. Permit renewal applications.**

This proposed section mirrors the current Section 1141.36 (relating to permit renewal applications), except for changing the citation in proposed subsection (b) to refer to this new proposed chapter. This proposed section provides the procedure for medical marijuana organizations applying for a permit renewal, in addition to specifying the information that must be included in the application.

**Section 1141a.37. Denial of renewal of a permit.**

This proposed section mirrors the current Section 1141.37 (relating to denial of renewal of a permit), except for changing the citations in proposed subsections (b), (d), and (e) to refer to this new proposed chapter. This proposed section provides the grounds upon which the

Department will deny the renewal of a medical marijuana organization's permit and outlines the obligations of a medical marijuana organization should it fail to file a permit renewal application or should the Department deny its application for a renewal permit.

**Section 1141a.38. Duty to report.**

This proposed section largely tracks the provisions in current Section 1141.38 (relating to duty to report), with two exceptions, as detailed below. This proposed section outlines the circumstances under which an applicant must report changes of information during the application process to the Department.

First, consistent with the revisions to proposed section 1141a.39 (relating to application for change in ownership of a medical marijuana organization), the Department proposes to amend subsection (b) to reflect that medical marijuana organizations only need to submit an application for a change in ownership, as opposed to an application for approval of a change of ownership. This revision reflects the fact that the Department does not approve equity transactions of medical marijuana organizations. Instead, the Department only approves the suitability of the individuals affiliated with medical marijuana organizations. Second, the citations in subsections (b) and (c) are revised to refer to this new proposed chapter.

**Section 1141a.39. Application for change in ownership of a medical marijuana organization.**

This proposed section replaces the current Section 1141.39 (relating to application for approval of a change in ownership of a medical marijuana organization). This proposed section substantially amends the provisions in current Section 1141.39, as detailed below.

*Title.*

This proposed section omits the words “approval of a” from the title of current Section 1141.39. Consistent with the proposed amendments to Section 1141a.38 discussed above, the Department proposes to clarify that it only determines the suitability of the individuals affiliated with medical marijuana organizations and does not approve a medical marijuana organization’s equity transaction.

*Subsection (a).*

This proposed subsection provides that medical marijuana organizations are required to submit an application for change in ownership to the Department in the event of an impending change in ownership involving a change in control. This proposed subsection deviates from the current subsection (a) in two ways: (1) it omits the words “approval of a” when discussing the application for a change in ownership, for the same reasons as discussed above; and (2) it revises the citation to refer to this new proposed chapter.

*Subsection (b).*

This proposed subsection provides that an application for a change of ownership will not be considered complete until the applicant pays the necessary fees. In replacing this subsection, the Department proposes to omit the current subsection (b) in its entirety, as it does not reflect the internal process currently used to evaluate affiliation of individuals

with a medical marijuana organization. Proposed subsection (b) tracks the substantive requirements of the current subsection (c). This proposed subsection deviates from the current subsection (c) in three ways: (1) it omits the words “approval of a” when discussing the application for a change in ownership, for the same reasons discussed above; (2) it revises the citation to refer to this new proposed chapter; and (3) it removes “the Department may reject an incomplete application” as this language does not reflect current practice.

*Subsection (c).*

This proposed subsection mirrors the current subsection (d), except for revising the citation to refer to this new proposed chapter. Under this proposed subsection, medical marijuana organizations will be required to provide all of the information required by proposed section 1141a.29 (relating to initial permit application) for each individual involved in the change of ownership.

*Subsection (d).*

This proposed subsection provides that a medical marijuana organization’s change in ownership without the Department’s knowledge and written approval of all individuals affiliated with the medical marijuana organization would be a violation of the act and this proposed part. This proposed subsection is modeled after the current subsection (f). The Department works with the medical marijuana organization to obtain all necessary information. This proposed subsection revises the current subsection (f) and includes the amended language as proposed subsection (d). Current subsection (f) provides that a change in ownership occurring without the Department’s “prior written approval of the change as provided in this section” is a violation, whereas this proposed subsection omits

that language and provides that a change in ownership that occurs without the Department’s “knowledge and written approval of all individuals affiliating with the medical marijuana organization” is a violation. This revision reinforces the fact that the Department only determines the suitability of the individuals affiliated with a medical marijuana organization and does not approve a medical marijuana organization’s equity transactions.

Finally, in proposing to replace current subsection (d), the Department proposes to delete current subsection (e) in its entirety to eliminate a process that is not currently utilized.

**Section 1141a.40. Application for approval of a change in location of an operational facility.**

This proposed section mirrors the current Section 1141.40 (relating to application for approval of a change in location of a facility), with three exceptions, as detailed below. This proposed section provides the procedure in which an operational facility may apply to relocate. This proposed section outlines the applicant’s responsibilities with respect to the content of the application, duties after receiving approval, and grounds for denial of an application. Compared to the current Section 1141.40, this proposed section deviates in three ways. (1) it adds the word “operational” to the title and to subsections (a) and (b), consistent with the proposed revisions to sections 1141a.27-.28 (relating to general requirements for applications; fees); (2) it removes “authorized under a permit” from subsections (a) and (b), as the language is unnecessary; and (3) it revises subsection (a) to refer to this new proposed chapter.

**Section 1141a.41. Application for approval of alteration of a facility.**

This proposed section mirrors the current Section 1141.41 (relating to application for approval of alteration of a facility), except for changing the citation in proposed subsection (b) to refer to this new proposed chapter. This proposed section provides that, as a general rule, a medical marijuana organization may not alter its facility after the issuance of a permit. This proposed section further provides that a medical marijuana organization wishing to make such an alteration must submit an application to do so if the proposed alteration involves one or more of the scenarios delineated in proposed subsection (b)(1)-(3).

**Section 1141a.42. Failure to be operational.**

This proposed section mirrors the current Section 1141.42 (relating to failure to be operational), except for changing the citation in proposed subsection (d) to refer to this new proposed chapter. This proposed section requires a medical marijuana organization to notify the Department that it is operational within six months from the date the Department issues the permit. The Department will then conduct an inspection to determine whether the medical marijuana organization is operational. Failure to adhere to its operational timeline will require the medical marijuana organization to create a plan of correction to become operational. If the medical marijuana organization fails to comply with its plan of correction within 90 days of the Department approving the plan, the Department may take disciplinary action.

**Section 1141a.43. Closure of a facility.**

This proposed section mirrors the current Section 1141.43 (relating to closure of a facility), except for changing the citations in proposed subsections (c)(3) and (d) to refer to this new proposed chapter. This proposed section outlines the procedure for a medical marijuana facility to close a facility. A medical marijuana organization that intends to close a facility must provide proper notice and a closure plan to the Department, which must be approved by the Department. This proposed section also lists activities in which a medical marijuana organization is prohibiting from engaging after providing notice of its intention to close a facility.

**Section 1141a.44. Insurance requirements.**

This proposed section mirrors the current Section 1141.44 (relating to insurance requirements). This proposed section requires a medical marijuana organization to obtain and maintain an adequate amount of insurance coverage for its activities, facilities, and equipment. This proposed section further provides that a medical marijuana organization must obtain and maintain adequate workers' compensation insurance coverage.

**Section 1141a.45. Inspection and investigation.**

This proposed section mirrors the current Section 1141.45 (relating to inspection and investigation). This proposed section provides that the Department may conduct announced or unannounced inspections to ensure a medical marijuana organization's compliance with its permit, the act, and this proposed part, and specifies the elements of the inspections. This proposed section further provides the extent to which the Department

and its authorized agents may inspect a facility. The proposed section also outlines the penalty for a medical marijuana organization's failure to provide immediate access to its facility.

**Section 1141a.46. Reports.**

This proposed largely mirrors the current Section 1141.46 (relating to reports), except for proposed revisions to subsection (a), as detailed below.

*Subsection (a).*

This proposed subsection outlines the ongoing reports medical marijuana organizations must provide to the Department and details the required contents of the reports. Proposed revisions to subsections (a)(1) and (a)(2) require dispensaries and growers/processors to report the "average price per unit of medical marijuana products sold" rather than the "per-dose price." These revisions are necessary because a "dose" varies from one patient to another and from one product to another.

*Subsection (b).*

This proposed subsection mirrors the current subsection (b), which provides that the Department will aggregate the information submitted through these reports and publish it on the Department's website.

*Subsection (c).*

This proposed subsection mirrors the subsection (c), which provides that the Department may require ongoing reporting of operational and financial information.

*Subsection (d)*

This proposed subsection mirrors the current subsection (d), which provides that the Department may require any reports necessary to carry out its responsibilities under the Act and this proposed part.

**Section 1141a.47. General penalties and sanctions.**

This proposed section mirrors the current Section 1141.47 (relating to general penalties and sanctions), except for two revisions, as detailed below. This proposed section outlines the penalties and sanctions the Department may impose for violations of the act and this proposed part, which range from a written warning to revocation of a permit. This proposed section further provides that individuals who assist in the violation of the act or this proposed part are subject to civil penalties.

Proposed subsection (a) augments the list of reasons for which the Department may suspend or revoke a medical marijuana organization's permit by adding falsification of information on any application submitted to the Department. This proposed addition serves to underscore the Department's expectation that applicants be truthful in all submissions to the Department. The Department also proposes to delete the words "temporary regulations" from subsection (d). As this proposed rulemaking promulgates Chapter 1230a as permanent regulations, this deletion is a necessary byproduct.

**Section 1141a.48. Training.**

This proposed section mirrors the current Section 1141.48 (relating to training), except that the content is reorganized to clarify that principals, as well as employees, who have direct

contact with patients or caregivers or who physically handle medical marijuana plants, seeds and products must complete the training. This proposed section outlines who must undergo a two-hour training course developed by the Department, in addition to the information that must be included in the training. This proposed section further provides that the Department will make its training course available at no cost to medical marijuana organizations, and medical marijuana organizations must retain the attendance records for the training and make them available to the Department upon request.

**Section 1141a.49.                    Zoning.**

This proposed section mirrors the current Section 1141.49 (relating to zoning). This proposed section provides that medical marijuana organizations must meet the same municipal zoning and land use requirements as other similar facilities located in the same zoning district.

**Section 1141a.50.                    Advertising by a medical marijuana organization.**

This proposed section mirrors the current Section 1141a.50 (relating to advertising by a medical marijuana organization). This proposed section provides that medical marijuana organizations must be consistent with applicable federal regulations when advertising or marketing medical marijuana products, and before use, these materials must first be approved by the Department. This proposed section further provides that it 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.

**Section 1141a.51. Technical advisories.**

This proposed section mirrors the current Section 1141.51 (relating to technical advisories). This proposed section provides that the Department may publish technical advisories in the *Pennsylvania Bulletin* to provide guidance with respect to the Department's interpretation of the act and this proposed part, but that the advisories would not have the force of law or regulation.

**CHAPTER 1151a. GROWERS/PROCESSORS**

This proposed chapter replaces the current Chapter 1151 (relating to growers/processors - - temporary regulations). Proposed new sections and amendments to sections of the current temporary regulations are discussed more fully below.

**Section 1151a.21. Growers/processors generally.**

This proposed section mirrors the current Section 1151.21 (relating to growers/processors generally) except for changing the citation in proposed subsection (b)(1) to refer to this new proposed chapter. This proposed section provides that a grower/processor is under a continuing obligation to meet the qualifications necessary to receive a permit. This proposed section further provides that a grower/processor may not engage in growing/processing operations prior to being deemed operational by the Department; nor may a grower/processor employ someone under the age of 18 to work at its facility.

**Section 1151a.22. Plans of operation.**

This proposed section contains three proposed amendments to the current Section 1151.22 (relating to plans of operation), as detailed below. This proposed section provides that at the time the Department determines a grower/processor to be operational, the grower/processor must provide the Department a full and complete plan of operation for review. This proposed section also delineates the required components of this plan of operation and provides that a grower/processor shall make the plan of operation available to the Department upon request.

This proposed section adds subsection (c), requiring a grower/processor to comply with its plan of operation. This addition will ensure that growers/processors comply with the plans of operation submitted to the Department, which provide guidance as to how a grower/processor will handle specific events. Further, this proposed section revises the language in paragraph (a)(2)(ii) by replacing the word “visitors” with the phrase “individuals requiring access to the facility.” The Department proposes this revision to emphasize that grower/processor facilities are not open to the public and are not permitted to have non-essential visitors. Finally, this proposed section revises the citation in proposed subsection (a)(12) to refer to this new proposed chapter.

**Section 1151a.23. Grower/processor facilities.**

This proposed section mirrors the current Section 1151.23 (relating to grower/processor facilities), excepting a one-word change in subsection (b)(3). This proposed section provides that growing/processing operations must occur in a secure facility approved by

the Department. This proposed section further delineates areas that must be marked with proper signage, in addition to requiring that loading and unloading of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, or medical marijuana products into and from a transport vehicle must take place in an enclosed, secure, out of public sight area of the facility.

This proposed subsection revises subsection (b)(3) with respect to signage for limited access areas. Current subsection (b)(3) requires that limited access areas have a sign that states “Do Not Enter—Limited Access Area—Access Limited to Authorized Personnel and Escorted Visitors.” This proposed subsection replaces the word “visitors” with “individuals.” The Department proposes replacement of the term “visitor” to accentuate the fact that grower/processor facilities are not open to the public and are not permitted to have non-essential visitors.

**Section 1151a.24. Start-up inventory.**

This proposed section replaces the current Section 1151.24 (relating to start-up inventory). This proposed section contains multiple changes from the current provisions, as detailed below.

*Subsection (a).*

This proposed subsection provides that a grower/processor may obtain seeds from outside this Commonwealth to secure its start-up inventory. A grower/processor may obtain seeds from outside this Commonwealth during (1) the 30-day period after the Department deems the grower/processor operational or (2) any 30-day window established by the Department

if the Department deems it necessary. This proposed subsection is revised to remove references to “immature medical marijuana plants” as section 702(a) of the act only permits the importation of seeds from outside the Commonwealth. The Department proposes the additional 30-day window to provide growers/processors more flexibility in acquiring seeds if the Department determines that importation of additional seeds is necessary. Importation of additional seeds may be necessary in order to fulfill anticipated demand of medical marijuana products, and to ensure an ample supply of important medicine to persons in the Commonwealth in need of it.

*Subsection (b).*

Proposed subsection (b) mirrors the current subsection (b). This proposed subsection provides that a grower/processor may not obtain medical marijuana plants, as opposed to seeds, from outside this Commonwealth at any time.

*Subsection (c)*

Proposed subsection (c) requires that a grower/processor record in the electronic tracking system any seeds that it receives during a 30-day period under proposed subsection (a) within 24 hours of receiving the seeds. This proposed subsection is revised to remove “and immature medical marijuana plant” as section 702(a) of the act only permits the importation of seeds from outside the Commonwealth.

*Subsection (d).*

The current subsection (d) provides that “[a]fter the 30-day period in subsection (a) a grower/processor shall only grow medical marijuana plants from seeds or immature medical marijuana plants located physically in its facility, or purchase seeds, immature medical marijuana plants or medical marijuana plants from another grower/processor.” The

proposed subsection (d), necessitated by the change to proposed subsection (a), modifies existing language to incorporate any additional 30-day window that may be provided for the importation of seeds.

**Section 1151a.25. Access to grower/processor facilities.**

The Department proposes several substantive changes the current Section 1151.25 (relating to visitor access to grower/processor facilities).

*Title*

Current Section 1151.25 is entitled “Visitor access to grower/processor facilities.” This proposed section is entitled “Access to grower/processor facilities.” This change proposes removal of the term “visitor” to accentuate the fact that grower/processor facilities are not open to the public.

*Subsection (a).*

This proposed subsection provides that grower/processor facilities may not be open to the general public. If someone who is not approved to enter a facility requires access to that facility for purposes related to the work of the facility, the individual will be required to sign a log detailing the need for entry and will also be required to wear a temporary identification badge while on site and in the facility. This proposed subsection clarifies who may have access to a facility, and for what purpose.

*Subsection (b).*

This proposed subsection requires individuals to present a government-issued photo identification in order to enter a grower/processor facility. The current subsection (b) provides that “visitors” must present proper identification; this proposed subsection

replaces “visitors” with “individuals,” consistent with the Department’s removal of the term “visitor” from the proposed regulations.

*Subsections (c) and (d).*

These proposed subsections mirror the current provisions. Proposed subsection (c) provides that individuals under the age of 18 are not permitted in a grower/processor facility. Proposed subsection (d) provides that a grower/processor must post proper signage at its facility.

*Subsection (e).*

This proposed subsection largely mirrors the current subsection (e), with some minor changes. This proposed subsection provides the Department’s expectations of a grower/processor that is admitting an individual into its facility. The changes from the current subsection include: (1) replacing the word “visitor” with “individual,” and (2) requiring that the individual detail the need for entry in the log. These changes are consistent with the Department’s intent to remove the word “visitor” where possible, and to ensure that individuals entering grower/processor facilities are entering for the proper reasons.

*Subsection (f).*

This proposed subsection provides the content and retention requirements for the log that individuals must sign upon entry to a grower/processor facility. Consistent with the rest of this proposed section, this proposed subsection changes the wording of the current regulations by replacing the word “visitor” with words or phrases similar to corresponding revisions to other subsections in this section.

*Subsection (g).*

This proposed subsection mirrors the current regulatory provision. This proposed subsection provides that nothing in proposed section 1151a.25 will limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government officials, from entering any area of a grower/processor site or facility, if entrance is necessary to perform their functions and duties that pertain to the act or this proposed part.

*Subsection (h).*

This proposed subsection provides that grower/processor employees or other affiliated persons may not be compensated for granting access to a limited access area. The only change to the language of the current subsection (h) is the Department's proposal to replace the word "visitor" with "individual," consistent with the rationale explained above.

**Section 1151a.26. Security and surveillance.**

This proposed section mirrors the current Section 1151.26 (relating to security and surveillance), except for two changes, as detailed below. This proposed section details the requirements of a grower/processor's security and surveillance systems and the inspection and servicing requirements. This proposed section further provides requirements with respect to access to rooms containing security and surveillance monitoring equipment and access.

This proposed section amends the current regulation in two ways. First, proposed subsection (b)(5) permits more than one employee to be assigned to monitor the security

system, whereas the current subsection only permits one employee to be assigned. Second, proposed subsection (d) requires that all entrances to and exits from a grower/processor facility must be securely locked “at all times,” as opposed to only during nonworking hours, as provided by the current subsection. The Department proposes these changes to ensure the safety and security of a grower/processor facility.

**Section 1151a.27. Requirements for growing and processing medical marijuana.**

This proposed section mirrors the current Section 1151.27 (relating to requirements for growing and processing medical marijuana), except for amending two subsections, as detailed below. This proposed section provides that a grower/processor may only use pesticides, fungicides, and herbicides approved by the Department of Agriculture and that the Department will periodically publish the list of approved pesticides, fungicides, and herbicides in the Pennsylvania Bulletin. This proposed section also requires a grower/processor to use approved pesticides, fungicides, and herbicides in a manner approved by the Department of Agriculture based on Federal law and regulations. A grower/processor must also log all actions taken to detect pests or pathogens and the measures taken for control. This proposed section requires a grower/processor to: use appropriate nutrient practices; use fertilizer as appropriate to support healthy plant growth; and maintain records of fertilizer and growth additives used.

This proposed section amends two subsections in the current Section 1151.27. First, the phrase “additional active ingredients or materials” in current subsection (f) is replaced with

the newly-defined term “added substance” for the purposes of clarity. Further, proposed subsection (f) adds paragraphs (i) and (ii) to provide guidance on what the Department will consider when determining whether to approve an added substance. Second, the current subsection (h)(3) provides that growers/processors only process parts of the medical marijuana plant that “[c]ontain a level of mold, rot or other fungus or bacterial diseases acceptable to the Department.” The proposed subsection changes that language to more clearly read that a grower/processor may only process parts of the medical marijuana plant that “[d]o not contain levels of mold, rot or other fungus or bacterial diseases above the minimum levels acceptable to the Department.”

**Section 1151a.28. Forms of medical marijuana.**

This proposed section mirrors the current Section 1151.28 (relating to forms of medical marijuana). This proposed section lists the six acceptable forms of medical marijuana that a grower/processor may process, in addition to providing that a grower/processor may not manufacture, produce, or assemble any medical marijuana product, instrument or device without the prior written approval of the Department.

**Section 1151a.29. Limit on medical marijuana processing.**

This proposed section mirrors the current Section 1151.29 (relating to limit on medical marijuana processing), excepting the revisions noted below. This proposed section provides that medical marijuana or medical marijuana products must have a specific concentration of total THC and total CBD, in addition to reporting the concentrations of delineated cannabinoids and listing them on the product’s label. Further, this proposed

section provides that within six months after the Department deems a grower/processor to be operational, a grower/processor must provide the Department a forecast of its medical marijuana production and form and notify the Department of potential increases or decreases within the following six months.

This proposed section differs from the current Section 1151.29 in two ways. First, proposed subsection (a) is revised to replace the full name of each cannabinoid on the product label with the abbreviation—as each is a defined term—in addition to requiring that the amount of Delta-8 THC be disclosed on the product label. These revisions are aimed at providing transparency with respect to the cannabinoids in medical marijuana products.

Second, proposed subsection (b) requires a grower/processor to “promptly” notify the Department of anticipated increases or decreases in production; the current subsection (b) requires the grower/processor to notify the Department “immediately.” This proposed amendment provides a slightly expanded time frame for a grower/processor to notify the Department of a potential increase or decrease in production of medical marijuana or medical marijuana products.

**Section 1151a.30. Inventory data.**

This proposed section mirrors the current Section 1151.30 (relating to inventory data). This proposed section specifies the data elements to be included in a grower/processor’s inventory and requires a grower/processor to maintain the listed data in its electronic

tracking system, in addition to requiring that a grower/processor establish inventory controls, and that the inventory information be maintained in an electronic record.

**Section 1151a.31. Storage requirements.**

This proposed section mirrors the current Section 1151.31 (relating to storage requirements), except for amending a citation in subsection (a) to refer to this new proposed chapter. This proposed section requires a grower/processor to ensure that its facility maintains a locked storage area for its products, and that these areas are kept in a clean and orderly condition.

**Section 1151a.32. Equipment, operation and maintenance.**

This proposed section mirrors the current Section 1151.32 (relating to equipment, operation and maintenance). This proposed section requires a grower/processor to: have a written process in place to maintain the sanitation and operation of its equipment, which must be provided to the Department upon request; routinely calibrate equipment used in operations; and maintain a log regarding the maintenance, cleaning, and calibration of its equipment.

**Section 1151a.33. Sanitation and safety in a facility.**

This proposed section mirrors the current Section 1151.33 (relating to sanitation and safety in a facility), except that “28 Pa. Code” is added to correct the incomplete citation in subsection (b). This proposed section requires that a grower/processor maintain sanitary conditions to limit potential for contamination, in accordance with the requirements listed in subsection (a), including, for example, frequent cleaning and sanitizing, proper removal

of trash, and protection against pests. Further, this proposed section states that any employee coming into direct contact with medical marijuana is subject to restrictions in 28 Pa. Code § 27.153 (relating to restrictions on food handlers). This proposed section also requires a grower/processor to provide potable water, cleansers, and handwashing facilities, as well as clean restroom facilities. Finally, this proposed section requires a grower/processor to comply with state and local building codes.

**Section 1151a.34. Packaging and labeling of medical marijuana products.**

This proposed section makes several substantive changes to the current Section 1151.34 (relating to packaging and labeling of medical marijuana products), as described below.

*Subsection (a).*

This proposed subsection, which mirrors the current subsection (a), provides that a grower/processor must package and label its products at its facility, and that the original seal may not be broken except for testing purposes at an approved laboratory.

*Subsection (b).*

This proposed subsection lists the general requirements for medical marijuana product packaging. The current subsection (b)(3) provides that packaging must be “[l]ight resistant or opaque, or both.” This proposed subsection revises that provision and requires that packaging be opaque and removes the option to be “light resistant.” This revision effectuates the Department’s intent that packaging not be transparent.

*Subsection (c).*

This proposed subsection, which mirrors the current subsection (c), requires a grower/processor to identify each process lot of medical marijuana with a unique identifier.

*Subsection (d).*

This proposed subsection requires that all packaging and labeling be approved by the Department and sets out the information that must be included on each label. The Department proposes to expand upon the requirements in the current subsection (d) by: (1) requiring that all packaging receive prior written approval of the Department; (2) requiring labels to list the species and percentages of all cannabinoids and individual terpenes; (3) requiring that labels be firmly affixed to the container directly holding medical marijuana as well as outer packaging; and (4) requiring that THC be the first number in a THC:CBD ratio, when the labeling includes a ratio. These revisions minimize patient confusion caused by medical marijuana packaging, and also ensure that individuals and law enforcement officials can readily determine if a medical marijuana product was purchased at a dispensary. This proposed subsection otherwise mirrors the current subsection (d), except for technical revision to subsection (d)(2) to correct syntax.

*Subsection (e).*

This proposed subsection mirrors the current subsection (e). This proposed subsection specifies the design and other elements that may not be included on a label.

**Section 1151a.35.                   Transportation of medical marijuana.**

This proposed section mirrors the current Section 1151.35 (relating to transportation of medical marijuana), with one exception in subsection (b)(4).

*Subsection (a).*

This proposed subsection provides the guidelines for the transportation of medical marijuana and medical marijuana products – transporting only between specified hours;

allowing for third-party contracting; prohibiting transport outside the Commonwealth; and requiring use of GPS tracking.

*Subsection (b).*

This proposed subsection requires the vehicles used to transport medical marijuana to be insured, unmarked, and temperature controlled with secure cargo areas. The current subsection (b)(4) requires that vehicles engaged in the transportation of medical marijuana “[d]isplay current State inspection stickers and maintain a current State vehicle registration.” This proposed subsection revises that provision to read that transportation vehicles must “[m]aintain current State inspection and vehicle registrations.” This revision allows for the possible elimination of inspection stickers in the future, as has been done with registration stickers.

*Subsection (c).*

This proposed subsection requires medical marijuana transport vehicles to be staffed with at least two individuals, one of whom must always remain with the vehicle, who: are licensed drivers, wear plain clothing, carry identification, and have access to communication.

*Subsections (d)-(h).*

These proposed subsections provide that transportation vehicles are subject to inspection and require: products in transport must be concealed from outside view; direct transportation from a grower/processor facility to a medical marijuana dispensary or laboratory where unloading must promptly occur; a grower/processor must immediately report to the Department any accidents, losses, or diversions of product that occur during transport; and a grower/processor must daily notify the Department of its delivery schedule.

**Section 1151a.36. Transport manifest.**

This proposed section mirrors the current Section 1151.36 (relating to transport manifest), except for revising one citation in subsection (c) to refer to this new proposed chapter. This proposed section requires a grower/processor to generate and maintain an electronic transport manifest, documenting information involved in all deliveries. This transport manifest is subject to inspection by the Department upon request. Proposed subsection (a) details the information that must be contained in the manifest. Proposed subsection (b) details specific chain of custody requirements for the transportation of seeds, plants, and other medical marijuana products. Proposed subsection (c) specifies the transportation requirements for seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products. Proposed subsection (d) requires a grower/processor to provide a copy of the manifest to the delivery recipient. Subsection (e) requires a grower/processor to provide a copy of the manifest to the Department and other governmental officials if requested.

**Section 1151a.37. Transportation of seeds, immature medical marijuana plants and medical marijuana plants.**

This proposed section mirrors the current Section 1151.37 (relating to transportation of seeds, immature medical marijuana plants and medical marijuana plants), except for revising three cross-references in subsection (c) to refer to this new proposed chapter. This proposed section provides a that grower/processor may only transport seeds, immature medical marijuana plants, and medical marijuana plants within this Commonwealth.

**Section 1151a.38. Evidence of adverse loss during transport.**

This proposed section mirrors the current Section 1151.38 (relating to evidence of adverse loss during transport), with one exception detailed below. This proposed section outlines a grower/processor's duties in the event of an unresolved discrepancy in the transport manifest upon delivery. This proposed section also requires a grower processor to report suspected theft or diversion of product to the Department; to investigate a discrepancy in the transport manifest; to amend its plan of operation if necessary to prevent future discrepancies; and to submit a report of the investigation to the Department.

The current subsection (a) provides that a grower/processor must refuse acceptance of a delivery in the event of any discrepancy in the transport manifest. Proposed subsection (a) requires a grower/processor to refuse delivery only when the discrepancy has not been resolved. This revision eliminates unnecessary delay in product delivery to dispensaries and, ultimately, to patients.

**Section 1151a.39. Electronic Tracking System.**

This proposed section provides that a grower/processor must use an electronic tracking system prescribed by the Department. This proposed section mirrors the current Section 1151.39 (relating to electronic tracking system), except for omitting the obsolete language that the Department will provide notice of the electronic tracking system to be used by growers/processors, as the Department published this information in the *Pennsylvania Bulletin* at the time the system was implemented.

**Section 1151a.40. Management and disposal of medical marijuana waste.**

This proposed section mirrors the current Section 1151.40 (relating to management and disposal of medical marijuana waste). This proposed section provides the obligations of a grower/processor with respect to the collection, storage, and disposal of medical marijuana waste. Specifically, all unused, surplus, returned, contaminated, or expired medical marijuana waste must be rendered unusable and incapable of ingestion and composted or disposed of according to municipal waste procedures or according to laws pertaining to hazardous waste.

**Section 1151a.42. Complaints about or recall of medical marijuana products.**

This proposed section mirrors the current Section 1151.42 (relating to complaints about or recall of medical marijuana products), with two exceptions, as detailed below. This proposed section provides that in the event of a complaint of an adverse event from using medical marijuana, a dispensary must notify the Department and the grower/processor from which it purchased the medical marijuana and outlines the grower/processor's subsequent investigatory and reporting obligations. Further, this proposed section addresses processes and procedures in the event of a voluntary or mandatory recall of medical marijuana or medical marijuana products, subject to penalties for noncompliance; specifies the information that must be entered into the electronic tracking system; and specifies the requirements of a recall plan.

This proposed section includes two amendments to the current regulations. First, proposed subsection (a)(1) requires that growers/processors “immediately” investigate complaints; the current regulation does not impose this immediacy requirement. Second, this proposed section adds subsection (h), authorizing the Department to initiate a mandatory recall upon receipt of information that any medical marijuana product poses a risk to public health and safety. These amendments underscore the Department’s goals of product quality and patient safety.

**Section 1151a.43. Pesticides.**

This proposed section mirrors the current Section 1151.43 (relating to pesticides), except that language was added in subsection (d) to clarify that the Department of Agriculture, which enforces the Pesticide Control Act, coordinates with the Department. This proposed section requires that the use of pesticides by a grower/processor be in accordance with the applicable laws in this Commonwealth, subject to oversight by the Department and the Pennsylvania Department of Agriculture. Further, this proposed section outlines the recordkeeping, record retention, and record production requirements associated with pesticide application, prescribes the pesticide active ingredients that a grower/processor may use, and defines terms relevant to this proposed section, including select terms used in the statutes cited in this proposed section.

**Section 1151a.44. Treatment and quarantine orders.**

This proposed section mirrors the current Section 1151.44 (relating to treatment and quarantine orders). This proposed section provides that the Department, in conjunction

with the Pennsylvania Department of Agriculture, may issue and carry out a treatment order against a grower/processor in the event that the grower/processor fails or refuses to eradicate a plant pest found at its facility. Further, this proposed section permits the Department of Agriculture, acting with the cooperation of the Department, to establish a quarantine if necessary to prevent the dissemination of plant pests and outlines the requirements in the event a quarantine is established.

### **CHAPTER 1161a. DISPENSARIES**

This proposed chapter replaces the current Chapter 1161 (relating to dispensaries -- temporary regulations). Proposed new sections and amendments to sections of the current temporary regulations are discussed more fully below.

#### **Section 1161a.22.                   Dispensaries generally.**

This proposed section mirrors the current Section 1161.22 (relating to dispensaries generally), except for revising a citation in subsection (b)(1) to refer to the new proposed Chapter 1141a. This proposed section provides that a dispensary is under a continuing obligation to meet the qualifications necessary to receive a permit. This proposed section further provides that a dispensary may not engage in dispensing operations prior to being deemed operational by the Department, may not employ someone under the age of 18, and may not allow a patient to administer medical marijuana in the facility unless the patient is also an employee.

**Section 1161a.23.                   Dispensing medical marijuana products.**

This proposed section mirrors the current Section 1161.23 (relating to dispensing medical marijuana products). This proposed section provides that a dispensary may only dispense to individuals who present a valid identification card; specifies the necessary prerequisites the dispensary must complete before dispensing medical marijuana products and before completing a transaction, including information that must be listed on a receipt, and recordkeeping requirements.

**Section 1161a.24.                   Limitations on dispensing.**

This proposed section mirrors the current Section 1161.24 (relating to limitations on dispensing). This proposed section provides that a dispensary may only dispense medical marijuana or medical marijuana in a quantity or form provided for on the patient's certification and permitted by the act or these proposed regulations. This proposed section also prohibits a dispensary from dispensing more than a 30-day supply of medical marijuana to a patient and not before the patient has exhausted all but a 7-day supply of medical marijuana.

**Section 1161a.25.                   Licensed medical professionals at facility.**

This proposed section mirrors the current Section 1161.25 (relating to licensed medical professionals at facility), with one addition, as detailed below. This proposed section provides that a physician or pharmacist must be present at the facility during operating hours and, if a permittee operates more than one facility under the same permit, a physician assistant or certified nurse practitioner may cover the other sites. Further, this proposed

section provides training requirements and continuing education standards for physicians, pharmacists, physician assistants, and certified nurse practitioners. This section also prohibits a practitioner or physician from issuing patient certifications while at the facility.

Compared to the current Section 1161a.25, proposed subsection (b) provides that a facility's "physician, pharmacist, physician assistant and certified registered nurse practitioner may rotate coverage of facilities as long as a physician or pharmacist is always present at one of the facilities." This addition clarifies that a dispensary authorized to operate more than one facility may allow the physician and pharmacist to rotate coverage to the secondary and tertiary dispensaries, as opposed to being limited to covering only the primary location.

**Section 1161a.26.                   Dispensary Facilities.**

This proposed section modifies the current Section 1161.26 (relating to dispensary facilities) in two ways, as detailed below. This proposed section imposes restrictions with respect to dispensary facilities and amenities. It also provides that individuals under the age of 18 may not enter a dispensary unless the individual is a patient or accompanied by a parent, guardian, or caregiver. This proposed section further provides signage requirements for specific areas of the facility.

This proposed section amends the current regulations in two ways. First, proposed subsection (b)(1) provides that a dispensary may not be located within 1,000 feet of "a public, private or parochial school, or a day-care center providing services to children under

the age of 18, measured from the property line of a public, private or parochial school nearest to the dispensary to the nearest physical wall of the dispensary.” This change clarifies that “school” is not intended to mean post-secondary schools and further defines how the 1,000-foot setback will be measured. This proposed section retains the authority of the Department to waive this requirement.

Second, proposed subsection (e)(1) provides that signage in limited access areas must state that access is limited to authorized personnel and escorted “individuals,” as opposed to the word “visitors” found in the current subsection (e)(1). This change is proposed to remove references to “visitors” wherever possible, as discussed elsewhere in this Preamble.

**Section 1161a.27. Items and services provided at a dispensary.**

This proposed section substantially revises the current Section 1161.27 (relating to items and services provided at a dispensary), as detailed below.

*Subsection (a).*

Beyond amending the regulatory citation to refer to this new proposed chapter, this proposed subsection mirrors the current regulatory provision. This proposed subsection provides that a dispensary may only dispense medical marijuana in forms prescribed in proposed section 1161a.23(b)(2) (relating to dispensing medical marijuana products).

*Subsections (b) and (c).*

These proposed subsections mirror the current subsections (b) and (c). These proposed subsections respectively provide that a dispensary may only purchase medical marijuana products from a grower/processor and that, with prior written approval from the

Department, a dispensary may sell instruments, devices, and services related to the use of medical marijuana products.

*Subsection (d).*

Aside from revising one citation to refer to the new proposed Chapter 1151a, this proposed subsection mirrors the current subsection (d). This proposed subsection provides that dispensaries may dispense a medical marijuana product with a THC concentration of less than 0.3% if purchased from a grower/processor that has obtained prior Department approval.

*Subsection (e).*

This proposed subsection delineates prohibited actions for a dispensary. Specifically, dispensaries may not (1) provide medical marijuana product at no cost unless the patient is approved for financial assistance by the Department; (2) make purchases conditional upon the patient purchasing a medical device at the facility or a separate facility; (3) deliver, or contract with a third party to deliver medical marijuana; and (4) sell items and services unrelated to the use of medical marijuana products. This proposed subsection removes the current prohibition on advertising activities, as that provision caused confusion. The removal of this subsection does not, however, negate the general requirement in proposed section 1141a.50(b) (relating to advertising by a medical marijuana organization) that all promotional, advertising, and marketing materials must be approved by the Department prior to use. Further, this proposed subsection revises the prohibition on delivering medical marijuana products by prohibiting a dispensary from contracting delivery to third parties, in addition to prohibiting a dispensary from delivering to a patient or caregiver, and by adding a prohibition on the sale of items unrelated to the use of medical marijuana. These

revisions seek to limit the services a dispensary may provide to a patient or caregiver that are unrelated to the sale of medical marijuana products.

**Section 1161a.28. Labels and safety inserts.**

This proposed section mirrors the current Section 1161.28 (relating to labels and safety inserts), with two exceptions, as detailed below. This proposed section sets forth the requirements of what must, and what may not, be listed on a label, in subsections (c) and (d), respectively, in addition to requiring, in subsection (b), that any product sold to a patient be fully sealed and labeled. Further, proposed subsection (c) requires a dispensary to inspect labels to ensure that the label contains all required information and is firmly affixed to the container holding medical marijuana, and proposed subsection (e) prescribes standards for safety inserts.

Compared to the requirements in current Section 1161.28, this proposed section adds the requirements that that all cannabinoids and terpenes and corresponding percentages be listed on the label and that a label be firmly affixed to a container directly holding medical marijuana. These revisions seek to ensure that law enforcement may readily discern the difference between packaging containing legitimate medical marijuana and illegal substances, in the event of a patient's interaction with law enforcement. In addition, the changes provide patients and caregivers with more information regarding the products they seek to purchase.

**Section 1161a.29. Plans of operation.**

This proposed section mirrors the current Section 1161.29 (relating to plans of operation), with two exceptions, as detailed below. This proposed section provides that upon the Department determining a dispensary to be operational, the dispensary must provide the Department with its plan of operation. This proposed section outlines what must be included in a plan of operation and requires that a dispensary provide its plan of operation to the Department during inspections of the site and facility and at any time upon request.

Proposed subsection (a)(2)(ii) replaces the word “visitors” with “individuals requiring access to the facility.” This change is proposed to remove references to “visitors” wherever possible, as discussed elsewhere in this Preamble. Proposed subsection (c) adds the requirement that a dispensary comply with its plan of operation. This addition ensures that a dispensary adheres to the plan of operation submitted to the Department, in addition to informing the Department as to how a dispensary would handle specific events.

**Section 1161a.30. Access to dispensary facilities.**

The Department proposes several substantive changes to the current Section 1161.30 (relating to visitor access to dispensary facilities), as detailed below.

*Title*

Current Section 1161.30 is entitled “Visitor access to dispensary facilities.” This proposed section is entitled “Access to dispensary facilities.” This change proposes removal of the term “visitor” to emphasize that dispensaries are not open for general visitation.

*Subsection (a).*

The current subsection (a) provides that a dispensary must post a sign at each entrance indicating that the premises are under constant video surveillance and that no one under the age of 18 is permitted to enter unless the individual is a patient or accompanied by a parent, guardian, or caregiver. The proposed amendments include adding language to the sign indicating that only employees, patients, and caregivers may enter, and that anyone under the age of 18 entering the dispensary must be a patient and accompanied by a parent. This proposed section clarifies that a dispensary is open only to employees, cardholders, and individuals requiring access to provide goods or services.

*Subsection (b).*

Proposed subsection (b) mirrors the current subsection (b) and provides that only authorized employees may enter limited access areas in a dispensary.

*Subsection (c).*

Proposed subsection (c) requires individuals to present a government-issued photo identification in order to enter a dispensary. The current subsection (c) provides that “visitors” must present proper identification; this proposed subsection eliminates the word “visitor” consistent with the Department’s removal of the term “visitor” from the regulations. The proposed new language clarifies that the subsection applies to any individual who is not approved to enter the facility who requires access in order to provide goods and services to the facility and requires the individual to sign a log and detail the need for entry to the facility.

*Subsection (d).*

Proposed subsection (d) details a dispensary’s obligations when admitting an individual to its facility, such as requiring the entrant to sign a log detailing the need for entry and to

wear a temporary identification badge while in the facility. Similar to proposed Section 1151a.25 (relating to access to grower/processor facilities), proposed subsection (d) revises the current subsection (d) to replace the term “visitor” with “individual.”

*Subsection (e).*

This proposed subsection provides the content and retention requirements for the log that individuals must sign upon entry to a dispensary. Consistent with the rest of this proposed section, this proposed subsection (e) changes the wording of the current subsection (e) by replacing the word “visitor” with words or phrases similar to corresponding revisions to other subsections in this section.

*Subsection (f).*

Proposed subsection (f) mirrors the current subsection (f). This proposed subsection provides that nothing in proposed section 1161a.30 will limit the right of the Department or its authorized agents, or State or local law enforcement or other Federal, State or local government officials from entering any area of a grower/processor site or facility, if entrance is necessary to perform their functions and duties that pertain to the act or this proposed part.

*Subsection (g).*

Proposed subsection (g) provides that dispensary employees or other affiliated persons may not be compensated for granting access to a limited access area. The only change to the language of the current subsection (d) is the Department’s proposal to replace the word “visitor” with “individual,” consistent with the rationale explained above.

**Section 1161a.31. Security and surveillance.**

This proposed section mirrors the current Section 1161.31 (relating to security and surveillance), except for the changes detailed below. This proposed section requires that a dispensary establish and maintain security and surveillance systems to the specifications provided within this proposed section. Further, this proposed section prescribes lighting requirements and limits access to rooms containing surveillance monitoring equipment.

This proposed section amends the current Section 1161a.31 in three ways. First, this proposed section allows dispensaries to designate multiple employees to continuously monitor the security and safety of a facility, whereas the current requirement only permits the designation of one employee. This revision provides dispensaries greater flexibility in ensuring the efficacy of their security systems while also not requiring the monitoring of these systems by a single person. Second, this proposed section requires that a dispensary install “commercial grade, nonresidential doors and door locks” on all external doors of the facility, which is not currently required by subsection (c). This change ensures the safety and security of each facility. Third, this proposed section requires that entrances to and exits from a dispensary be locked at all times, as opposed to just during nonworking hours, as currently required by subsection (d). This change seeks to ensure the safety and security of facilities.

**Section 1161a.32. Inventory data.**

This proposed section mirrors the current Section 1161.32 (relating to inventory data). This proposed section lists the inventory information that must be maintained in the electronic

tracking system, in addition to requiring a dispensary to establish inventory controls and conduct monthly reviews and annual comprehensive inventories, and specifies what information must be recorded as a result of inventory reviews.

**Section 1161a.33. Storage requirements.**

This proposed section mirrors the current Section 1161.33 (relating to storage requirements), except for revising a citation in subsection (a) to refer to the new proposed Chapter 1151a. This proposed section provides that dispensaries must have separate and locked limited access areas for the storage of defective medical marijuana products, as described in this proposed section. This proposed section also provides that all storage areas must be maintained in a clean and orderly condition.

**Section 1161a.34. Sanitation and safety in a facility.**

This proposed section mirrors the current Section 1161.34 (relating to sanitation and safety in a facility), except that except “28 Pa. Code” was added to correct the incomplete citation in subsection (b) and the word “visitor” was deleted from subsections (c) and (d) for the reasons explained elsewhere in this Preamble. Proposed subsections (a) and (b) prescribe sanitation requirements and expectations for a dispensary facility and employees therein; proposed subsections (c) and (d) require adequate bathroom and hand-washing facilities; and proposed subsection (e) requires a dispensary to comply with all State and local building codes.

**Section 1161a.35.                      Transportation of medical marijuana products.**

This proposed section mirrors the current Section 1161.35 (relating to transportation of medical marijuana products), with two exceptions, as detailed below. This proposed section provides that a dispensary may deliver medical marijuana products to medical marijuana organizations, subject to requirements delineated in proposed subsection (a). This proposed section also outlines the requirements with respect to the storage of medical marijuana products during transportation in proposed subsection (b); delivery drivers in proposed subsection (c); and transportation in proposed subsections (d) and (e). Further, proposed subsections (f) and (g) impose reporting requirements for specified events, and proposed subsection (h) subjects transport vehicles to inspection at the Department's request.

The only amendments from the current regulation are in proposed subsection (b). Subsection (b)(1) requires that vehicles transporting medical marijuana products be "equipped with a secure lockbox located within a locking cargo area," as opposed to the requirement in current subsection (b) that such vehicles be "equipped with a secure lockbox or locking cargo area." This change clarifies that medical marijuana products are to be securely transported in a lockbox located within a locking cargo area to minimize opportunity for diversion. Further, proposed subsection (b)(4) requires that these vehicles maintain current state inspection and vehicle registrations, whereas the current regulation requires current vehicle registration and the display of a state inspection sticker. This revision allows for the possible elimination of inspection stickers in the future, as has been done with registration stickers.

**Section 1161a.36. Transport manifest.**

This proposed section mirrors the current Section 1161.36 (relating to transport manifest), with one exception, as detailed below. Proposed subsections (a) and (b) provide that every transport vehicle shall generate a transport manifest, specifies the information that must be contained in the manifest, and details requirements for delivery to multiple facilities. The one amendment to the current regulation is that proposed subsection (c) requires that seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, and medical marijuana products be transported in a secure lockbox located within a locked cargo area, whereas the current regulation requires that the product be packaged in a shipping container. Proposed subsection (d) requires a dispensary to provide a copy of the manifest to the delivery recipient. Subsection (e) requires a dispensary to provide a copy of the manifest to the Department and other governmental officials if requested. This amendment harmonizes this proposed section with the amendments to the requirements of proposed section 1161a.35 (relating to transportation of medical marijuana products) to prevent diversion.

**Section 1161a.37. Evidence of adverse loss during transport.**

This proposed section mirrors the current Section 1161.37 (relating to evidence of adverse loss during transport), with one exception detailed below. This proposed section outlines a dispensary's duties in the event of an unresolved discrepancy in the transport manifest upon delivery. This proposed section also requires a dispensary to report suspected theft or diversion of product to the Department; to investigate a discrepancy in the transport

manifest; to amend its plan of operation if necessary to prevent future discrepancies; and to submit a report of the investigation to the Department.

The current subsection (a) provides that a dispensary must refuse acceptance of a delivery in the event of any discrepancy in the transport manifest. This proposed subsection (a) requires a dispensary to refuse delivery only when the discrepancy has not been resolved. This revision eliminates unnecessary delay in product delivery to dispensaries and, ultimately, to patients.

**Section 1161a.38.                      Complaints about or recall of medical marijuana products.**

This proposed section mirrors the current Section 1161.38 (relating to complaints about or recall of medical marijuana products), except for revising a citation to refer to the new proposed Chapter 1151a. This proposed section provides that dispensaries must notify the Department and the grower/processor from which it purchased the medical marijuana product immediately upon becoming aware of a complaint made to the dispensary by an individual who experienced an adverse event resulting from interaction with a medical marijuana product. If the grower/processor were to recall the product, the dispensary is required to cease dispensing the item in question and coordinate a return of the recalled product.

**Section 1161a.39. Electronic tracking system.**

This proposed section provides that a dispensary must use an electronic tracking system prescribed by the Department. This proposed section mirrors the current Section 1161.39 (relating to electronic tracking system), except for omitting the obsolete language that the Department will provide notice of the electronic tracking system to be used by growers/processors, as the Department published this information in the *Pennsylvania Bulletin* at the time the system was implemented.

**Section 1161a.40. Application for additional dispensary locations.**

This proposed section mirrors the current Section 1161.40 (relating to application for additional dispensary locations), except for revising a citation to refer to the new proposed Chapter 1151a. This proposed section provides that an applicant for a dispensary permit may identify a primary location and up to two additional dispensary locations in its application or at a later date, using a form prescribed by the Department and following the initial permitting requirements set forth in proposed section 1114a.29 (relating to initial permit application), subject to subject to the payment of fees specified in subsection (c) and the Department's approval.

**CHAPTER 1171a. LABORATORIES**

This proposed chapter replaces the current Chapter 1171 (relating to laboratories -- temporary regulations). Proposed new sections and amendments to sections of the current temporary regulations are discussed more fully below.

**Section 1171a.22. Laboratories generally.**

This proposed section mirrors the current Section 1171.22 (relating to laboratories generally), except for revising citations in subsection (a) to refer to this new proposed chapter. This proposed section prohibits a laboratory from collecting or testing medical marijuana samples unless the laboratory has been approved by the Department under § 1171a.23 (relating to approval of laboratories) and has entered into a written contract with the grower/processor under § 1171a.29 (relating to testing requirements). This proposed section requires the Department to post a list of approved laboratories on its website and provides general requirements with respect to: (1) laboratory duties; (2) director responsibilities and employee qualifications; (3) prohibitions on ownership; (4) duration of the Department's approval; and (5) nontransferability of the Department's approval.

**Section 1171a.23. Approval of laboratories.**

This proposed section mirrors the current Section 1171.23 (relating to approval of laboratories), except for revising a citation in subsection (b)(8) to refer to this new proposed chapter. This proposed section provides that a laboratory wishing to become an approved laboratory must submit a completed application to the Department, including the information required in proposed subsections (b) and (d), the submission of which amounts to consent to an investigation of any person, information, or location the Department deems appropriate in order to approve or deny the application. Under this proposed section, the Department may grant approval based upon its determination that the applicant is financially and professionally suitable to conduct the required testing.

**Section 1171a.24. Suspension or revocation of an approval issued to a laboratory.**

This proposed section mirrors the current Section 1171.24 (relating to suspension or revocation of an approval issued to a laboratory). This proposed section provides that the Department may suspend or revoke a laboratory's approval if the laboratory engages in unethical practices, fails to maintain proper standards for reporting accuracy, or fails to comply with the act or this proposed part. Further, this proposed section delineates other conduct for which the Department may revoke a laboratory's approval.

**Section 1171a.25. Renewal of an approval issued to a laboratory.**

This proposed section mirrors the current Section 1171.25 (relating to renewal of an approval issued to a laboratory), except for revising a citation to refer to this new proposed chapter. This proposed section provides the timeframe in which an approved laboratory must submit an application for renewal.

**Section 1171a.26. Stability testing and retention of samples.**

This proposed section mirrors the current Section 1171.26 (relating to stability testing and retention of samples). This proposed section provides that an approved laboratory must conduct required stability testing of samples collected from growers/processors to ensure product potency and purity and accurate expiration dating, and that the laboratory must properly store those tested samples for one year.

**Section 1171a.27. Sampling procedures for testing.**

This proposed section mirrors the current Section 1171.27 (relating to sampling procedures for testing). Proposed subsection (a) requires a laboratory to ensure its employees follow established sample preparation procedures. Proposed subsections (b) and (c) outline the elements that a laboratory's policies and sampling procedures must include.

**Section 1171a.28. Selection protocol for samples.**

This proposed section mirrors the current Section 1171.28 (relating to selection protocol for samples). This proposed section provides that an employee of an approved laboratory may only enter a grower/processor facility for the purpose of identifying and collecting samples, subject to procedures regarding chain of custody. This proposed section also specifies the samples that a laboratory employee must identify and collect from a grower/processor facility.

**Section 1171a.29. Testing requirements.**

The Department proposes several changes to the current Section 1171.29 (relating to testing requirements), as detailed below.

*Subsections (a) and (b).*

These proposed subsections mirror the current regulatory provisions. These proposed subsections provide that an approved laboratory must enter into a written contract with a growers/processor prior to conducting testing and submit a request for testing through the electronic tracking system.

*Subsection (c).*

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.

*Subsections (d), (e), and (f).*

These proposed subsections mirror the current regulatory provisions. These proposed subsections provide the minimum elements for which a laboratory must test; that testing samples must be conducted with a statistically significant number and size of samples and methodologies approved by the Department; and that testing is prohibited on samples in the delineated circumstances.

*Subsection (g).*

This proposed subsection (g) specifies tracking and disposal requirements. Where the current subsection (g) requires that all tests be entered into the electronic tracking system, this proposed subsection (g) provides that only testing performed on samples of harvest lots and process lots must be entered into the electronic tracking system, which and allows for additional tests to be performed without being entered into the electronic tracking system. Many permittees have requested the ability to conduct additional testing prior to harvesting. Additionally, a citation has been amended to refer to this new proposed chapter and the new proposed Chapter 1151a.

**Section 1171a.30. Standards for testing.**

This proposed section mirrors the current Section 1171.30 (relating to standards for testing). This proposed section requires that an approved laboratory 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.

**Section 1171a.31. Test results and reporting.**

The Department proposes several changes to the current Section 1171.31 (relating to test results and reporting), as detailed below, in addition to changing citations to reflect this new proposed chapter and the new proposed Chapter 1151a (relating to growers/processors).

*Subsection (a).*

Aside from revising citations to refer to this new proposed chapter, this proposed subsection (a) mirrors the current subsection (a). This proposed subsection lists the tests to which the testing requirements of the proposed chapter apply: testing on harvest lots and process lots.

*Subsection (b).*

This proposed subsection (b) has been amended to clarify that only testing performed on harvest lots and process lots are required to be entered into the electronic tracking system. The current subsection (b) requires all test results to be entered into the system. This amendment allows a permittee to conduct additional testing outside of the two required to be entered into the system. Further, this proposed subsection (b) revises a citation to refer to this new proposed chapter.

*Subsection (c).*

This proposed subsection (c) mirrors the current subsection (c), except as detailed below. This proposed subsection (c) provides the procedure for a sample that fails testing. This proposed subsection allows a failed sample to be re-tested by the same laboratory. If the initially failed sample were then to pass re-testing, proposed subsection (c)(2) requires a different laboratory to confirm that passing test. Proposed subsection (c)(3) allows the Department to opt to reject the confirming result from the approved laboratory. The term “confirming” was added to subsection (c)(3) as a grammatical clarification. If the Department rejects the confirming result, or if the sample were to fail again, under proposed paragraphs (3), the lot is required to be disposed of in accordance with proposed Section 1151a.40 (relating to management and disposal of medical marijuana waste). Proposed paragraph (4) had been added to clarify the expectation that a re-tested sample that fails is required to be disposed of in accordance with proposed Section 1151.40. Finally, citations have been amended to refer to this new proposed chapter and new proposed Chapter 1151a.

*Subsection (d).*

This proposed subsection (d) mirrors the current subsection (d). This proposed subsection requires that a laboratory notify the Department and the approved laboratory of its intent to re-test a sample that failed a test or test another sample from the same harvest batch, harvest lot, or process lot.

*Subsection (e).*

This proposed subsection (e) requires a laboratory to provide a grower/processor a certificate of analysis that reports the results of the testing, which must include the

delineated information. Compared to the current subsection (e), paragraph (1) of this proposed subsection utilizes defined abbreviations for certain chemical compounds, including compounds that have been added to the proposed paragraph (1), that must be included in the analysis, whereas the current subsection (e) provides the full names.

**Section 1171a.32. Quality assurance program.**

This proposed section mirrors the current Section 1171.32 (relating to quality assurance program). This proposed section requires that an approved laboratory establish and implement a quality assurance program to ensure accuracy and delineates the components that the quality assurance program must include.

**Section 1171a.33. Transporting samples.**

This proposed section mirrors the current Section 1171.33 (relating to transporting samples), except for revising citations in subsection (a) to refer to the new proposed Chapter 1151a. This proposed section requires that the samples must be transported in accordance with proposed Sections 1151a.35 and 1151a.36 (relating to transportation of medical marijuana; and transport manifest). Further, this proposed section requires that samples be transported from a grower/processor to an approved laboratory in a manner that adequately protects the integrity and composition of the samples from outside interference.

**Section 1171a.34. Department request for testing.**

This proposed section mirrors the current Section 1171.34 (relating to department request for testing). This proposed section provides that the Department, in its discretion, may

identify and collect samples for testing by an approved laboratory, and the approved laboratory must provide a written report of the results within seven days or sooner if requested by the Department.

**Section 1171a.35. Laboratory reporting.**

The Department proposed to make several changes to the current Section 1171.35 (relating to laboratory reporting), as detailed below.

*Subsection (a).*

This proposed subsection (a) lists the specific information a laboratory must enter into the electronic tracking system when testing a sample collected pursuant to proposed Section 1171a.28(c) (relating to testing of samples from harvest lots and process lots). Compared to the current subsection (a), this proposed subsection (a) requires that only those tests conducted pursuant to proposed Section 1171a.28(c), as opposed to all tests conducted, must be entered into the electronic tracking system. Additionally, citations are amended to refer to this new proposed chapter.

*Subsection (b).*

This proposed subsection provides that an approved laboratory maintain a certificate of analysis for four years and amends the current subsection to include those test results not required to be entered into the electronic tracking system. Additionally, proposed amendments to this subsection add paragraph (1), which requires an approved laboratory to immediately provide to the Department an electronic copy of a certificate of analysis for those test results that are not required to be entered into the electronic tracking system, and

paragraph (2), which modifies the current subsection (b) to apply only to results entered into the electronic tracking system.

*Subsection (c).*

This new proposed subsection (c) provides that the Department may conduct an investigation based on the results of any certificate of analysis. This proposed subsection is added to ensure product quality and patient safety.

**Section 1171a.36. Advertising.**

This proposed section mirrors the current Section 1171.36 (relating to advertising). This proposed section prohibits a laboratory from advertising or promoting its services to the general public. This proposed section clarifies that personal solicitation by a laboratory employee is considered advertising or promotional marketing. It also provides that a laboratory may only advertise to a grower/processor those services performed on site, subject to prior Department approval. Further, this proposed section provides that a laboratory may erect signage at its facility, subject to compliance with local zoning requirements and this proposed section.

**Section 1171a.37. Ownership prohibition.**

This proposed section mirrors the current Section 1171.37 (relating to ownership prohibition). This proposed section delineates those individuals who may not have a management, financial (direct or indirect), or other ownership interest in an approved laboratory.

**Section 1171a.38. Appeals.**

This proposed section mirrors the current Section 1171.38 (relating to appeals), except for amending a citation to refer to the new proposed Chapter 1230a (relating to practice and procedure). This proposed section provides that all actions of the Department under this proposed chapter are governed by Chapter 5, Subchapter A of 2 Pa.C.S. and its accompanying regulations, as modified by proposed Chapter 1230a.

**CHAPTER 1181a. PHYSICIANS AND PRACTITIONERS**

This proposed chapter replaces the current Chapter 1181 (relating to physicians and practitioners -- temporary regulations). Proposed new sections and amendments to sections of the current temporary regulations are discussed more fully below.

**Section 1181a.22. Practitioners generally.**

This proposed section mirrors the current Section 1181.22 (relating to practitioners generally), excepting three technical amendments, as detailed below. This proposed section requires that a practitioner meet continuing qualifications to be registered with the Department and may not issue patient certifications prior to becoming registered. This proposed section also requires a practitioner to notify a dispensary of a patient's adverse reaction to medical marijuana dispensed by that dispensary. Further, this proposed section permits a practitioner to petition the Medical Marijuana Advisory Board to review any proposed change to the currently listed serious medical conditions for which medical marijuana could be beneficial. Where the current Section 1181a.22 provides that the Medical Marijuana Advisory Board will establish a procedure to effectuate this review

process, this proposed section no longer contains that language, as the Medical Marijuana Advisory Board has already created that process. Additionally, a citation in proposed subsection (b) has been amended to refer to this new proposed chapter, and a reference to the statute has been deleted in proposed subsection (d).

**Section 1181a.23. Medical professionals generally.**

This proposed section mirrors the current Section 1181.23 (relating to medical professionals generally), except for revising a citation in subsection (b) to refer to this new proposed chapter. This proposed section provides that, like the requirements for a registered practitioner, the requirements to be a registered medical professional are an ongoing responsibility to maintain. The proposed section also provides that a medical professional may not assume any duties at a dispensary until all requirements are satisfied. This proposed section further requires that a medical professional notify the practitioner listed on the patient certification of any adverse reaction suffered by the patient as a result of interaction with a medical marijuana product purchased at the dispensary.

**Section 1181a.24. Physician registration.**

The language in this proposed section substantively mirrors the current Section 1181.24 (relating to physician registration), except for revising a citation in subsection (c) to refer to this new proposed chapter but is reorganized for clarification. This section as currently written in the temporary regulation implies that that a physician may not apply for registration as a practitioner unless the physician holds an active, unrestricted medical license and is determined by the Department to be qualified to treat patients with serious

medical conditions. The proposed section relocates the physician licensing requirement in current subsection (a)(1) to proposed subsection (a); deletes the current subsection (a)(2) and replaces it with proposed new subsection (c), to clarify that the Department determines approval to issue patient certifications based on the information submitted in the application; and revises the current subsection (c) to be proposed subsection (d). With this reorganization, the section more clearly provides for licensing qualifications to apply in subsection (a), followed by application requirements in subsection (b), and ending with a determination of approval to issue patient certifications based on the submitted application in subsection (c). This proposed section further provides that the Department may only list a physician on the practitioner registry after the physician has completed the training course required in proposed Section 1181a.32 (relating to training) and met all other requirements for registration.

**Section 1181a.25. Practitioner registry.**

This proposed section mirrors the current Section 1181.25 (relating to practitioner registry). This proposed section provides that the Department will maintain a practitioner registry for use by patients or caregivers, and that inclusion in the registry is subject to annual review by the Department to ensure that the practitioner remains qualified.

**Section 1181a.26. Denial, revocation or suspension of a practitioner registration.**

This proposed section mirrors the current Section 1181.26 (relating to denial, revocation or suspension of a practitioner registration), except for revising a citation in subsection (c)

to refer to this new proposed chapter. This proposed section provides the grounds upon which the Department may deny, revoke, or suspend a practitioner's registration. The proposed section also prohibits a physician who has been denied registration or has had that registration revoked or suspended from accessing, issuing, modifying, or copying a patient's certification. Further, this proposed section provides that a physician may reapply if the circumstances leading to registration denial, revocation, or suspension have resolved.

**Section 1181a.27. Issuing patient certifications.**

This proposed section mirrors the current Section 1181.27 (relating to issuing patient certifications). This proposed section specifies the conditions under which a practitioner may issue a patient certification, as well as specifying the information that is required on a patient certification. This proposed section also requires a practitioner to provide a copy of a completed patient certification to the patient or the patient's caregiver and to the Department, as well as to retain a copy in the patient's file.

**Section 1181a.28. Modifying a patient certification.**

This proposed section mirrors the current Section 1181.28 (relating to modifying a patient certification). This proposed section provides that a practitioner may not modify the form of medical marijuana products specified on a patient certification for 30 days from the date the receipt is entered into the electronic tracking system unless the practitioner notifies the Department. This proposed section also requires a practitioner to provide a copy of a modified patient certification to the patient or the patient's caregiver and to the Department, as well as to retain a copy in the patient's file.

**Section 1181a.29.                    Revocation of a patient certification.**

This proposed section mirrors the current Section 1181.29 (relating to revocation of a patient certification). This proposed section provides that a practitioner must immediately notify the Department that a patient's circumstances have changed in a manner that would affect the patient's certification, for example, the patient no longer has the serious medical condition for which he or she was certified. The proposed section also provides that the Department will revoke the patient's certification upon receiving such notification. Further, this proposed section provides that a practitioner may withdraw the issuance of a patient certification at any time. The proposed section also provides that the Department will immediately notify the medical marijuana cardholder of a certification revocation and enter the information into the electronic tracking system.

**Section 1181a.30.                    Prescription drug monitoring program.**

This proposed section mirrors the current Section 1181.30 (relating to prescription drug monitoring program). This proposed section requires a practitioner to review the Prescription Drug Monitoring Program prior to issuing or modifying a patient certification to determine whether the controlled substance history of the patient would impact the patient's use of medical marijuana products. The proposed section also specifies the reasons for which a practitioner may access the Prescription Drug Monitoring Program.

**Section 1181a.31. Practitioner prohibitions.**

This proposed section mirrors the current Section 1181.31 (relating to practitioner prohibitions), except for adding subsection (g). This proposed section lists the prohibitions for practitioners, including: (1) accepting any form of remuneration for issuing patient certifications other than a fee for the patient consultation; (2) holding a direct or economic interest in a medical marijuana organization; (3) advertising as a certifying physician; (4) issuing a patient certification for personal use or for a family or household member; (5) acting as a caregiver for a patient certified by the practitioner; and (6) receiving or providing medical marijuana samples. In addition, new proposed subsection (g) prohibits a practitioner from charging patients excessive fees. The Department is proposing the change due to patient complaints of practitioners taking advantage of the certification process by charging excessive lab testing, follow-up, or other fees not initially disclosed. Section 301(a)(11) of the act provides that the Department “shall collaborate as necessary with other Commonwealth agencies or contract with third parties as necessary to carry out the provisions of this act.” The Department will collaborate with the Department of State (DOS), which licenses physicians, and refer for investigation complaints that a practitioner is engaging in unscrupulous billing practices. DOS will investigate and, if DOS finds a violation of the Medical Practice Act of 1985, 63 P.S. §§ 422.1-422.51a, or the Osteopathic Medical Practice Act, 63 P.S. §§ 271.1-271.18, DOS will impose sanctions. If DOS suspends, revokes, limits or otherwise restricts the practitioner’s license, the practitioner will be removed from the medical marijuana physician registry pursuant to 28 Pa. Code § 1181a.26(a).

**Section 1181a.32. Training.**

This proposed section mirrors the current Section 1181.32 (relating to training), except for revising a citation in subsection (a) to refer to this new proposed chapter. This proposed section specifies those individuals who must complete a four-hour training course prescribed by the Department and the requirements of that training course. Further, this proposed section provides that completion of the training course qualifies as continuing education credits by certain medical boards, and that individuals who completed the training course must submit documentation to that effect to the Department. Finally, this proposed section provides that the Department will provide on its website a list of approved training providers.

**Section 1181a.33. Appeals.**

This proposed section mirrors the current Section 1181.33 (relating to appeals), except for revising a citation to reflect the new proposed Chapter 1230a (relating to practice and procedure). This proposed section provides that all actions of the Department under this proposed chapter are governed by Chapter 5, Subchapter A of 2 Pa.C.S. and its accompanying regulations, as modified by proposed chapter 1230a.

**CHAPTER 1191a. PATIENTS AND CAREGIVERS**

This proposed chapter replaces the current Chapter 1191 (relating to patients and caregivers -- temporary regulations). Proposed new sections and amendments to sections of the current temporary regulations are discussed more fully below.

**Section 1191a.22. Patient and caregiver registry.**

This proposed section mirrors the current Section 1191.22 (relating to patient and caregiver registry), except for revising a citation in subsection (b) to refer to this new proposed chapter. This proposed section provides that the Department will maintain a registry of patients and caregivers and lists the information that must be included in the registry. This proposed section also provides that the information contained in that registry is confidential and not subject to disclosure. Further, this proposed section provides that a caregiver may waive this confidentiality requirement and consent to providing the caregiver's name and contact information to the patient.

**Section 1191a.23. Patients and caregivers generally.**

This proposed section mirrors the current Section 1191.23 (relating to patients and caregivers generally), except for revising a citation in subsection (b) to refer to this new proposed chapter. This proposed section provides that the qualifications to become a patient or caregiver are ongoing qualifications, and the Department may issue a certification card to those individuals who meet those qualifications. Further, this proposed section provides that the Department may, with sufficient showing of suitability, allow a person under the age of 21 to serve as a caregiver. Finally, this proposed section provides that a minor patient shall have a caregiver who meets the criteria specified in subsection (d).

**Section 1191a.24. Medical marijuana cardholder responsibilities.**

The Department proposes several changes to the current Section 1191.24 (relating to medical marijuana cardholder responsibilities), as detailed below.

*Subsection (a).*

This proposed subsection (a) lists the circumstances under which a medical marijuana cardholder must immediately contact the Department. Specifically, those instances include: (1) change of the cardholder's name or address; (2) practitioner withdrawal of a patient certification; (3) a patient's decision to discontinue the services of a caregiver; (4) a decision of a caregiver to no longer serve in such a capacity for the patient; and (5) a decision by patient to discontinue treatment from the practitioner who issued the patient certification. This proposed subsection (a) amends the current subsection (a) in two ways: (1) corrects a typographical error (changing "withdraw" to "withdrawal"); and (2) revises a citation to refer to the new proposed Section 1181a.29 (relating to revocation of a patient certification).

*Subsection (b).*

This proposed subsection (b) replaces the current subsection (b) in its entirety and removes the current regulatory requirement that the cardholder must return the identification card upon receiving notification from the Department that the cardholder has been removed from the registry or the patient certification has been revoked. Returning the card is not necessary because the card will be inactivated and rendered unusable. This proposed subsection (b) provides that a medical marijuana cardholder must apply for a replacement identification card within ten business days of discovering the loss or defacement of the identification card. This provision was moved from the current subsection 1191.28(f)

(relating to identification cards) as it is more appropriate under this section detailing cardholder responsibilities.

**Section 1191a.25. Application for, and issuance or denial of, identification cards.**

This proposed section mirrors the current Section 1191.25 (relating to application for, and issuance or denial of, identification cards), except for revising citations throughout to refer to this new proposed chapter and new proposed Chapters 1181a (relating to practitioners). This proposed section requires patient or caregiver identification card applicants to submit the proper application, complete with the information required in proposed subsections (b) and (d). Proposed subsection (c) details the procedure where an application designates a caregiver who is not authorized to serve as a caregiver. Applicants for a caregiver identification card are subject to a criminal background check and subsection (e) provides the grounds upon which an application may be denied.

Proposed subsection (f) provides that the Department will notify the applicant of an incomplete application and of the additional information that is required. Proposed subsection (g) provides the applicant with 60 days to submit the requested information. Finally, proposed subsections (h) and (i) provide that the Department will notify an applicant in writing of the reasons for denial of an application, allow the applicant to submit a new application following that denial, and permit the Department to decline consideration of a re-application that does not correct previously identified deficiencies.

**Section 1191a.26. Application fees.**

This proposed section mirrors the current Section 1191.26 (relating to application fees), except for two amendments, as detailed below.

*Subsections (a) and (b).*

These proposed subsections (a) and (b) mirror the current subsections (a) and (b). These proposed subsections provide that an applicant may pay no more than one \$50 fee in a twelve-month period for an identification card, unless the applicant is submitting a renewal application within the same twelve-month period or the applicant requires a replacement card, in which case the cardholder will pay \$25 for a replacement card.

*Subsection (c).*

This proposed subsection (c) provides that the Department may establish higher fees for the issuance of a second and subsequent replacement cards by publishing notice thereof in the *Pennsylvania Bulletin*. The current subsection (c) requires the Department to publish these fees every January. This proposed subsection eliminates the annual publication requirement if no changes are made.

*Subsection (d).*

This proposed subsection (d) allows the Department to waive or reduce card fees for financial hardship and provides that the Department will publish on its website the qualification for financial hardship. The current subsection (d) provides that this will occur every January. This proposed subsection eliminates the annual publication requirement if no changes are made.

**Section 1191a.27. Criminal background checks.**

This proposed section mirrors the current Section 1191.27 (relating to criminal background checks). This proposed section requires an individual applying for an identification card as a caregiver submit to fingerprints to the Pennsylvania State Police for the purpose of obtaining a criminal background check. This proposed section also provides that the Department reviews the individual's criminal history only to determine the caregiver's character, fitness, and suitability to serve in such a capacity.

**Section 1191a.28. Identification cards.**

This proposed section mirrors the current Section 1191.28 (relating to identification cards), with one exception, as detailed below. This proposed section provides that the Department will issue identification cards as soon as practicable, and requires that the card contain certain delineated information, including a photograph of the cardholder. Subsection (c) provides that the Department will not require a photograph if the applicant submits a statement that a photograph cannot be provided due to the applicant's religious beliefs. Further, this proposed section outlines the circumstances under which an identification card issued to a patient or caregiver will expire. This proposed section omits the requirement in current subsection (f) that cardholders apply for a replacement card within ten business days of discovering the loss or defacement of the card, as this requirement has been moved to proposed subsection 1191a.24(b) (relating to cardholder responsibilities).

**Section 1191a.29.                      Renewing an identification card.**

This proposed section mirrors the current Section 1191.29 (relating to renewing an identification card), with two exceptions, as detailed below. This proposed section provides that a cardholder shall submit an application for card renewal no later than 30 days prior to the expiration of the current card, and that a cardholder shall obtain a new or updated certification. Further, this proposed section provides that the identification card will not be valid beyond the stated expiration date and the Department may remove the individual from the patient and caregiver registry if the Department denies a renewal application or if the cardholder fails to submit a renewal application.

Compared to the current Section 1191.29, proposed subsection (a) has been revised to require a medical marijuana cardholder to submit a new patient certification at the time the cardholder submits an application for a new identification card only if the certification is expired. This change is proposed because the time in which a patient must submit a new certification may not coincide with the time in which the patient must obtain a new identification card. Additionally, the citation in subsection (a) has been revised to refer to the new proposed Chapter 1181a (relating to practitioners).

**Section 1191a.30.                      Revocation or suspension of identification card.**

This proposed section mirrors the current Section 1191.30 (relating to revocation or suspension of identification card), except for the few revisions detailed below. This proposed section provides the instances in which the Department may suspend or revoke a cardholder's identification card and that, in such an instance, the Department will notify

the cardholder of the Department's action. Further, this proposed section provides that if a patient's practitioner's registration has been revoked or suspended under proposed section 1181a.26 (relating to denial, revocation or suspension of a practitioner registration), or if a patient's practitioner withdraws the patient's patient certification under proposed section 1181a.29(c) (relating to revocation of a patient certification), the cardholder is required to obtain a new patient certification within 90 days of receiving notice from the Department or prior to the expiration of the identification card, whichever is sooner.

Compared to the current Section 1191a.30, proposed subsection (c) has been revised to reflect that a patient does not need to apply for a new medical marijuana identification card when a practitioner's registration has been revoked or suspended or a practitioner withdraws the patient's certification under section 1181a.29(c). Instead, proposed subsection (c) provides that a patient is required to obtain a new patient certification as explained above. Additionally, citations have been amended throughout this section to refer to the new proposed Chapter 1181a (relating to practitioners).

**Section 1191a.31. Obtaining medical marijuana products from a dispensary.**

This proposed section mirrors the current Section 1191.31 (relating to obtaining medical marijuana products from a dispensary), except for amending citations have been amended throughout this section to refer to the new proposed Chapters 1161a (relating to dispensaries) and 1181a (relating to practitioners). This proposed section provides that a medical marijuana cardholder may only obtain medical marijuana products from a

dispensary in accordance with proposed section 1161a.24 (relating to limitations on dispensing), and that the cardholder may only obtain medical marijuana products from a dispensary based on the recommendation provided in a valid patient certification that the dispensary may access through the electronic tracking system.

**Section 1191a.32. Medical marijuana patient authorization letters.**

This proposed section mirrors the current Section 1191.32 (relating to medical marijuana patient authorization letters), except for revising a citation to refer to this new proposed chapter and adding clarifying language to subsection (b), as detailed below. This proposed section provides that the Department will issue a medical marijuana patient authorization letter to a minor patient and may issue a patient authorization letter to an adult patient, instead of issuing an identification card. Proposed subsection(b) adds language to clarify that a patient authorization letter may be issued to an adult patient only when the patient's illness or infirmity permanently prevents the patient from visiting a dispensary. Further, this proposed section provides that when the minor patient who has been issued a patient authorization card turns 18, the patient is entitled to apply for an identification card. This proposed section also provides that a medical marijuana patient authorization letter confers the same rights and obligations, and is subject to the same terms and conditions, as apply to a medical marijuana cardholder, except that an identification card will be required for entry into a dispensary. Further, this proposed section provides that a patient who has been issued a medical marijuana patient authorization letter will not be required to pay an identification card application fee or an identification card renewal application fee.

The medical marijuana patient authorization letter is not intended to, and may not be, a substitute for a medical marijuana identification card, which is required to access a dispensary. The patient authorization letter may be used only to signify authorization to be in possession of, or to consume, medical marijuana. It was developed because schools and child care programs have requested documentary evidence that minor patients, who cannot get a photo identification card from the Pennsylvania Department of Transportation (PennDOT), the agency that verifies Pennsylvania addresses for the issuance of a medical marijuana identification card, are permitted to consume medical marijuana. The letter does not afford access to a dispensary or authorize a caregiver to dispense medical marijuana. All patients holding a patient authorization letter must have a caregiver, who has an identification card, who visits the dispensary and obtains medical marijuana on the patient's behalf and delivers the medication to the patient. This letter is also used to accommodate homebound patients who also cannot obtain a PennDOT photo identification card. The Department also developed the patient authorization letter because it does not want to require payment for an identification card (\$50.00 fee) from a patient who will never independently access a dispensary due to the patient's minor age or due to illness or infirmity that permanently prevents the patient from visiting a dispensary.

**Section 1191a.33. Appeals.**

This proposed section mirrors the current Section 1191.33 (relating to appeals), except for revising a citation to reflect the new proposed Chapter 1230a (relating to practice and procedure). This proposed section provides that all actions of the Department under this

proposed chapter are governed by Chapter 5, Subchapter A of 2 Pa.C.S., as modified by proposed Chapter 1230a.

## **CHAPTER 1211a. CLINICAL REGISTRANTS AND ACADEMIC RESEARCH CENTERS**

This proposed chapter replaces the current Chapter 1211 (relating to clinical registrants and academic research centers -- temporary regulations. Consistent with removing the definition of “certified ACRC” from Chapter 1141a, references to “certified” ACRC are removed from proposed subsections 1211a.25(b) and (d), 1211a.27(b)-(d), 1211a.27a, 1211a.30(c), 1211a.31(b), 1211a.32, 1211a.34, and 1211a.35. Other proposed amendments to sections of the current temporary regulations are discussed more fully below.

### **Section 1211a.22. Clinical registrants generally.**

This proposed section mirrors the current Section 1211.22 (relating to clinical registrants generally), except for revising citations to refer to this, and other, new proposed chapters. This proposed section provides that the qualifications to be a clinical registrant are ongoing qualifications. Further, this proposed section outlines the process of becoming a clinical registrant, including holding or applying for dispensary and grower/processor permits. This proposed section provides that the Department will not approve more than eight clinical registrants, and the clinical registrant may not engage in dispensing activities until it receives Department approval. Further, this proposed section provides that an approved clinical registrant may not dispense medical marijuana products until determined to be operational by the Department and the clinical registrant demonstrates ability to begin research within six months of becoming operational. Finally, this proposed section

provides that clinical registrants may dispense to a cardholders regardless of whether the patient is participating in a research study.

**Section 1211a.23.                    Limitation on permits.**

This proposed section mirrors the current Section 1211.23 (relating to limitation on permits). This proposed section provides that an approved clinical registrant may not hold more than one dispensary and one grower/processor permit. Further, this proposed section provides that an approved clinical registrant may dispense medical marijuana at up to six separate locations, each of which must dispense medical marijuana to conduct research, and that no more than three of those locations may be in the same medical marijuana region or county.

**Section 1211a.24.                    Capital requirements.**

This proposed section mirrors the current Section 1211.24 (relating to capital requirements), except for revising citations to refer to new proposed chapters. This proposed section outlines the capital requirements for a clinical registrant applicant, which must be affirmed via affidavit submitted with the application to become a clinical registrant, along with a release to allow the Department to verify this information.

**Section 1211a.25.                    Certifying ACRCs.**

This proposed section mirrors the current Section 1211.25 (relating to certifying ACRCs). This proposed section provides that the qualifications to become an ACRC are ongoing qualifications. This proposed section also provides that an accredited medical school may

become approved to be an ACRC by application and that the Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of the application and the time period for applying. This proposed section specifies the information that must be included in an application and provides that the Department will publish a list of the certified ACRCs on its publicly available website and in the *Pennsylvania Bulletin*.

**Section 1211a.26. Revocation of a certification of an ACRC.**

This proposed section mirrors the current Section 1211.26 (relating to revocation of a certification of an ACRC). This proposed section outlines the circumstances under which the Department will revoke the certification of an ACRC. Further, should such an event occur, the Department will provide written notice of the action, and the ACRC will receive an opportunity to retain its certification by submitting proof of corrective action within 90 days of receiving the notice from the Department.

**Section 1211a.27. Application for approval of a clinical registrant.**

This proposed section mirrors the current Section 1211a.27 (relating to application for approval of a clinical registrant), except for revising citations to refer to this, and other, new proposed chapters. This proposed section provides that an entity wishing to become a clinical registrant must apply to do so via application. This proposed section specifies the information that must be included in an application, some of which is confidential under the Right-to-Know Law, 65 P.S. §§ 67.101--67.3104, and not subject to disclosure. This proposed subsection also provides that the Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of the application and the time period

for applying. This proposed section further provides that an applicant may only include one certified ACRC in its application for approval as a clinical registrant.

**Section 1211a.27a. Research contracts.**

This proposed section mirrors the current Section 1211.27a (relating to research contracts). This proposed section provides that an applicant for approval as a clinical registrant shall provide with its application either (1) an executed agreement or (2) a letter of intent to enter into an agreement with a certified ACRC. This proposed section further provides that an applicant may submit more than one application, with separate applications identifying distinct certified ACRCs, and that although a certified ACRC may enter into a letter of intent with more than one clinical registrant applicant, it may only execute a research contract with one approved clinical registrant. Further, this proposed section provides that if more than one applicant for approval as a clinical registrant submits an application that includes a letter of intent with the same certified ACRC, the Department will follow the outlined prioritization in approving applications. Finally, this proposed section provides the minimum acceptable scores for a grower/processor and a dispensary permit application.

**Section 1211a.28. Request for conversion of an existing permit.**

This proposed section replaces the current Section 1211.28 (relating to request for conversion of an existing permit), except for revising citations to refer to this, and other, new proposed chapters. This proposed section provides that a dispensary or grower/processor permittee must submit a request for conversion of an existing grower/processor or dispensary permit with its application for approval as a clinical

registrant. This proposed section further provides that upon approval as a clinical registrant, the clinical registrant will surrender its current dispensary or grower/processor permit, which will increase the number of available grower/processor or dispensary permits available to the commercial market. Finally, this proposed section provides that an applicant may include additional dispensary locations in its request for conversion of an existing permit or may request additional dispensary locations at a later date.

**Section 1211a.29. Practices and procedures of research programs, projects or studies.**

This proposed section mirrors the current Section 1211.29 (relating to practices and procedures of research programs, projects or studies). This proposed section requires medical marijuana to be dispensed to a patient or caregiver as part of a research program in a form that conforms to the act or this proposed part. This proposed section further provides that medical marijuana may be dispensed from a clinical registrant directly to an ACRC in any form deemed safe by an institutional review board (IRB). This proposed section further provides requirements for research approval committees and IRBs, including (1) establishing policies and procedures, (2) reviewing research studies, and (3) ensuring each research study addresses the issues specified in proposed subsection (e).

**Section 1211a.30. Approval or denial of an application for approval of a clinical registrant.**

This proposed section mirrors the current Section 1211.30 (relating to approval or denial of an application for approval of a clinical registrant), except for revising citations to refer

to this and other new proposed chapters. This proposed section provides that an applicant shall be an approved clinical registrant upon the Department's approval of an application under proposed Section 1211.27 (relating to application for approval of a clinical registrant). This proposed section further provides that the Department may deny the application if the applicant has disclosed prior payments to a certified ACRC. This proposed section also specifies that prior to denying an application, the Department will issue written notice to the applicant and the applicant will have the opportunity to cure the prohibited payments by submitting to the Department a supplemental affidavit indicating that the certified ACRC or its affiliate has refunded to the applicant the prohibited payment. Further, this proposed section provides that an approved clinical registrant will have the same rights and obligations as a grower/processor or dispensary permittee, and a clinical registrant's dispensary and grower/processor permits will expire upon expiration, revocation, or nonrenewal of the clinical registrant's approval.

**Section 1211a.31. Renewal of approval of a clinical registrant.**

This proposed section mirrors the current Section 1211.31 (relating to renewal of approval of a clinical registrant), except for revising a citation to reflect the new proposed Chapter 1141a (relating to general provisions). This proposed section provides that the term of an approval of a clinical registrant will coincide with the term of the clinical registrant's grower/processor permit and dispensary permit, and that an approved clinical registrant will be required to renew its approval as part of its dispensary and grower/processor permit renewals. This proposed section further provides that the renewal application must be submitted on a form prescribed by the Department, must include the information specified

in subsection (b), and is subject to Department approval. Finally, this proposed section provides that the Department will not renew approval for a clinical registrant if the Department determines that none of the clinical registrant's dispensary locations is engaging in research and does not intend to engage in research within six months of renewal.

**Section 1211a.32. Revocation of approval of a clinical registrant.**

This proposed section mirrors the current Section 1211.32 (relating to revocation of approval of a clinical registrant), except for revising a citation to refer to this new proposed chapter. This proposed section outlines the circumstances under which a clinical registrant's approval will be revoked, including revocation or suspension of the clinical registrant's grower/processor or dispensary permit, revocation of the partnered ACRC certification, and lack of a research contract. This proposed section provides that the Department will issue written notice of its intention to revoke approval. Thereafter, the clinical registrant will have 90 days to contract with another certified ACRC that is not already contractually committed, or have its approval revoked.

**Section 1211a.33. Dispensing and tracking medical marijuana products.**

This proposed section mirrors the current Section 1211.33 (relating to dispensing and tracking medical marijuana products), except for revising a citation to refer to the new proposed Chapter 1161a (relation to dispensaries). This proposed section provides that the dispensary of an approved clinical registrant shall enter information into the electronic tracking system as required by the Department identifying patients who are enrolled in an

approved research program or research study, in addition to entering information about medical marijuana products dispensed to all patients and caregivers.

**Section 1211a.34. Prohibition.**

This proposed section mirrors the current Section 1211.34 (relating to prohibition). This proposed section provides that, except for reasonable remuneration specified in a research contract for the services to be performed or costs to be incurred by the certified ACRC, a certified ACRC may not solicit or accept anything of value from an approved clinical registrant or a principal or financial backer of an approved clinical registrant. Further, this proposed section clarifies that the prohibition does not apply to charitable contributions that are part of a history of giving to a certified ACRC established one year or more prior to the effective date of the act.

**Section 1211a.35. Reporting requirements.**

This proposed section mirrors the current Section 1211.35 (relating to reporting requirements). This proposed section outlines when an approved clinical registrant must provide the Department a report of the findings of a research activity. This proposed section further provides that the Department will publish these findings on its publicly available website and share them with other approved clinical registrants, ACRCs, or other persons the Department determines would benefit from the findings.

**Section 1211a.36. Sale or exchange.**

This proposed section mirrors the current Section 1211.36 (relating to sale or exchange), except for revising a citation to refer to this new proposed chapter. This proposed section outlines the items a grower/processor of a clinical registrant may sell or exchange with another grower/processor and provides that a grower/processor of a clinical registrant may only sell its medical marijuana products to its own dispensary or to a dispensary owned by another clinical registrant. This proposed section further provides that an approved clinical registrant may petition the Department to sell its medical marijuana products to a dispensary in the commercial market and specifies that the petition must include the report required by proposed Section 1211a.35 (relating to reporting requirements).

**Section 1211a.37. Appeals.**

This proposed section modifies the current Section 1211.37 (relating to appeals), as detailed below. This proposed section provides that all actions of the Department under this proposed chapter are governed by Chapter 5, Subchapter A of 2 Pa.C.S. and its accompanying regulations, as modified by the new proposed Chapter 1230a (relating to practice and procedure). This proposed section amends the current Section 1211.37 by adding the language that the accompanying regulations to 2 Pa. C.S. Chapter 5, as modified by proposed Chapter 1230a, apply to the appeal process. This proposed section also revises the citation to refer to the new proposed Chapter 1230a.

## **CHAPTER 1230a. PRACTICE AND PROCEDURE**

This proposed chapter replaces the current Chapter 1230 (relating to practice and procedure -- temporary regulations). Proposed amendments to sections of the current temporary regulations are discussed more fully below.

### **Section 1230a.21. Scope.**

This proposed section mirrors the current Section 1230.21 (relating to scope). This proposed section provides that this proposed chapter and the General Rules of Administrative Practice and Procedure govern practice and procedure before the Department in medical marijuana appeals.

### **Section 1230a.22. Definitions.**

This proposed section mirrors the current Section 1230.22 (relating to definitions). This proposed section provides definitions not referenced in proposed Section 1141a.21 (relating to definitions) and supplements the definitions in 1 Pa. Code § 31.3 (relating to definitions).

### **Section 1230a.23. Docket.**

This proposed section mirrors the current Section 1230.23 (relating to docket). This proposed section provides the general duties and address of the docket clerk for mailing of filings. Further, this proposed section provides that pleadings must be filed within prescribed time periods and are considered filed when received by the docket clerk. This

proposed section also provides that the clerk will maintain the docket, that the docket is available for public inspection, and that proposed subsections (a) through (e) supersede 1 Pa. Code §§ 33.11 and 33.51 (relating to execution; and docket).

**Section 1230a.24. Filing generally.**

This proposed section mirrors the current Section 1230.24 (relating to filings generally). This proposed section provides the general requirements for a filing to be accepted by the Department and provides for rejection or correction of deficient pleadings. This proposed section further provides that redundant, immaterial, or inappropriate pleadings may be stricken before being accepted for filing.

**Section 1230a.25. Effective date of adjudication, actions or order.**

This proposed section mirrors the current Section 1230.25 (relating to effective date of adjudication, actions or order). This proposed section provides that an adjudication, action, or order is effective as of the date of mailing unless specifically provided otherwise, and that proposed subsection (a) supersedes 1 Pa. Code § 31.14 (relating to effective dates of agency orders).

**Section 1230a.26. Representation.**

This proposed section mirrors the current Section 1230.26 (relating to representation). This proposed section provides that, except for an individual appearing on his own behalf, a party, corporation, or group of individuals acting in concert must be represented by an attorney in good standing and outlines how that representation must be effected. This

proposed section also provides that proposed subsections (a) through (d) supersede 1 Pa. Code §§ 31.21 through 31.23 (relating to appearance in person; appearance by attorney; and other representation prohibited at hearings).

**Section 1230a.38. Commencement, form and content of Notice of Appeal.**

This proposed section mirrors the current Section 1230.38 (relating to commencement, form and content of notice of appeal). This proposed section details the proper form of, and procedure for filing, a Notice of Appeal. This proposed section also provides that proposed subsections (a) through (g) supersede 1 Pa. Code §§ 35.5 through 35.7. and 35.20 (relating to informal complaints; and appeals from actions of the staff).

**Section 1230a.39. Timeliness of Notice of Appeal.**

This proposed section amends the current Section 1230.39 (relating to timeliness of notice of appeal), as detailed below. This proposed section provides that the timeliness of a Notice of Appeal is measured from the mailing date of the written notice of the action, and an untimely filed Notice of Appeal may be deemed an admission or be dismissed with prejudice. This proposed section further provides that the Department may file an answer and new matter to a Notice of Appeal within 30 days of service of the Notice, but is not required to do so.

This proposed section proposes two amendments. First, proposed subsection (a) provides that the timeliness of an appeal will be measured from the mailing date of the written notice of the action instead of the date the appellant receives the written notice, as specified in the

current subsection (a). This proposed amendment removes ambiguity relating to timeliness of appeals and removes the possibility for differing time periods for appeal. Second, proposed subsection (b) provides that an untimely filed Notice of Appeal may be deemed an admission or may be dismissed by the Department, instead of the language in the current section 1230.39 that one's "failure to file" a timely Notice of Appeal results in the same. This proposed amendment is a technical clarification. This proposed section also provides that proposed subsection (a) supersedes 1 Pa. Code §§ 35.5 through 35.7, 35.20, and 35.35 (relating to informal complaints; appeals from actions of the staff; and answers to complaints and petitions).

**Section 1230a.43. Orders to Show Cause, orders or petitions filed by the Office.**

This proposed section mirrors the current Section 1230.43 (relating to Orders to Show Cause, orders or petitions filed by the Office), except for the revisions detailed below. This proposed section provides that the Office may start an action by filing an Order to Show Cause. Proposed subsection (b) revises the current subsection (b) to provide that the date of service is the date indicated on the certificate of service, regardless of the method of service, as opposed service being deemed complete three days after the date on the certificate of service if service is effected by mail. This proposed amendment eliminates ambiguity as to the date of service. This proposed section also specifies the required content for an Order to Show Cause and provides the required format for a notice to respond. Finally, this proposed section provides that proposed subsections (a) through (d) supersede 1 Pa. Code § 35.14 (relating to orders to show cause).

**Section 1230a.44.                    Answers to Orders to Show Cause, orders or other petitions filed by the Office.**

This proposed section mirrors the current Section 1230.44 (relating to answers to orders to show cause, orders or other petitions filed by the Office), except for revising a citation to refer to this new proposed chapter. This proposed section outlines the content, form, and substance of responses to Orders to Show Cause, orders, or other petitions filed by the Office, in addition to providing penalties for failure to file a timely response. This proposed section also prohibits the filing of new matter or preliminary objections and specifies that proposed subsections (a) through (e) supersede 1 Pa. Code § 35.37 (relating to answers to orders to show cause).

**Section 1230a.45.                    Verifications and affidavits.**

This proposed section mirrors the current Section 1230.45 (relating to verifications and affidavits). This proposed section provides that a pleading or other document containing an averment of fact not appearing of record in the action or containing a denial of fact shall be personally verified in a manner prescribed by this proposed section by a party thereto or by an authorized officer of the party if a corporation or other business entity.

**Section 1230a.46.                    Entry of default judgment.**

This proposed section mirrors the current Section 1230.46 (relating to entry of default judgment). This proposed section provides that the Department, on motion of the Office, may enter default judgment against the respondent for failure to file within the required

time an answer to an Order to Show Cause, order or other petition, to which the respondent may answer and have an opportunity to be heard; default judgment may not be granted prior to the hearing and the filing of an answer.

**C. AFFECTED PERSONS**

Medical marijuana applicants, patients and their caregivers, as well as grower/processor and dispensary permittees and approved labs, will be required to comply with the provisions in this proposed rulemaking. Additionally, those individuals or entities that have not yet been issued a permit to receive, dispense, or prescribe medical marijuana as well as successful future applicants will be required to comply with the provisions contained in this proposed rulemaking.

**D. COST AND PAPERWORK ESTIMATE**

**1. Cost**

**a. Commonwealth**

The Department will experience increased demands to maintain compliance control over the Medical Marijuana Program. This increased demand will be handled by the existing Medical Marijuana Program complement. The Department does not expect that it will incur any cost increases as a result of this proposed rulemaking.

**b. Local Government**

The proposed rulemaking will impose no additional costs and have no negative fiscal impact upon political subdivisions. Further, the proposed rulemaking does not impose any additional burden of enforcement or review on political subdivisions.

**c. Regulated Community**

The proposed rulemaking will impose no additional costs upon medical marijuana cardholders and caregivers.

Grower/processor and dispensary permittees may experience minimal cost increases in complying with the revised policies regarding facility security and testing and reporting requirements imposed by this proposed rulemaking.

Practitioners will not experience any additional costs as a result of this proposed rulemaking.

**d. General public**

This proposed rulemaking will have no fiscal impact on the general public.

**2. Paperwork Estimates**

**a. Commonwealth and the Regulated Community**

This proposed rulemaking imposes no additional paperwork requirements on the Commonwealth or the regulated community.

**b. Local Government**

This proposed rulemaking imposes no additional paperwork requirements on local government.

**c. General Public**

This proposed rulemaking imposes no additional paperwork requirements on the general public.

**E. STATUTORY AUTHORITY**

The Department obtains its authority to promulgate regulations relating to the Medical Marijuana Program from the provisions of the Medical Marijuana Act (35 P.S. §§ 10231.101-10231.2110). The act provides the Department with the authority to promulgate all regulations necessary to carry out the provisions set forth in the act. (35 P.S. § 10231.301(b)). Further, under Section 301 of the act, the Department has (1) regulatory and enforcement authority over the growing, processing, sale, and use of medical marijuana in the Commonwealth, and (2) authority to promulgate all regulations necessary to carry out the provisions of the act. (35 P.S. § 10231.301(a)(3), (b)).

**F. EFFECTIVENESS AND SUNSET DATES**

The proposed rulemaking becomes effective upon publication in the *Pennsylvania Bulletin* as final-form rulemaking. No sunset date will be established. The Department will continually review and monitor the effectiveness of these regulations after they are published as final.

**G. REGULATORY REVIEW**

Under section 5(a) of the Regulatory Review Act, the act of June 30, 1989 (P.L. 73, No. 19) (71 P.S. § 745.5(a)), on February 16, 2020, the Department submitted a copy of these proposed regulations to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In addition to submitting the proposed regulations, the

Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department. A copy of this form is available to the public upon request.

Under section 5(g) of the Regulatory Review Act (71 P.S. § 745.5(g)), IRRC may convey any comments, recommendations, or objections to the proposed regulations within 30 days of the close of the public comment period. The comments, recommendations, or objections shall specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulation, by the Department, the General Assembly, and the Governor of comments, recommendation, or objections raised.

#### **H. CONTACT PERSON**

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposed regulations to John J. Collins, Director, Office of Medical Marijuana, Department of Health, Room 628, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120, (717) 547-3047, or by email to [RA-DHMMregulations@pa.gov](mailto:RA-DHMMregulations@pa.gov) within 30 days after publication of these proposed regulations in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions, or objections regarding the proposed regulations may do so by using the above number or address. Speech and/or hearing-impaired persons may submit comments, suggestions, or objections by calling the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

**Annex A**

**Title 28. HEALTH AND SAFETY**

**PART IX. MEDICAL MARIJUANA**

**CHAPTER 1131 (Reserved)**

**§§ 1131.1—1131.7 (Reserved).**

**CHAPTER 1141 (Reserved)**

**§§ 1141.21—1141.52 (Reserved).**

CHAPTER 1141a. GENERAL PROVISIONS

§ 1141a.21. Definitions.

The following words and terms, when used in this part, have the following meanings, unless the context clearly indicates otherwise:

*ACRC –Academic Clinical Research Center* -- An accredited medical school in this Commonwealth that operates or partners with an acute care hospital licensed and operating in this Commonwealth that has been approved and certified by the Department to enter into a contract with a clinical registrant.

*Accreditation body*—An organization which:

- (i) Certifies the competency, expertise and integrity of a laboratory and operates in conformance with the current version of International Organization Standard ISO/IEC 17011.
- (ii) Determines a laboratory's compliance with and conformance to the relevant standards established by the International Organization for Standardization, including ISO/IEC 17025.
- (iii) Is a signatory to the International Accreditation Cooperation Mutual Recognition Arrangement for Testing.

- (iv) Is not affiliated with a laboratory applicant for which it has or will issue a certificate of accreditation.

*Accredited medical school*--An institution that is:

- (i) Located in this Commonwealth.
- (ii) Accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation.

*Acute care hospital*--A facility having an organized medical staff that provides equipment and services primarily for inpatient medical care and other related services to persons who require definitive diagnosis or treatment, or both, for injury, illness, pregnancy or other disability and is licensed by the Department to operate as a hospital in this Commonwealth under the Health Care Facilities Act (35 P.S. §§ 448.101--448.904b) and the regulations promulgated thereunder.

*Act*—The Medical Marijuana Act (35 P.S. § § 10231.101—10231.2110).

*Added substance*— Any additional ingredient added to medical marijuana during or after processing that is present in the final product or any substance used to change the viscosity or consistency of a cannabinoid product.

*Adult patient*—A patient who is 18 years of age or older.

*Adverse event*—An injury resulting from the use of medical marijuana dispensed at a

dispensary. An injury includes physical harm, mental harm or loss of function.

*Adverse loss*—A loss, discrepancy in inventory, diversion or theft of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, funds or other property of a medical marijuana organization.

*Advertising*—The publication, dissemination, solicitation or circulation, for a fee, that is visual, oral, written or electronic to induce directly or indirectly an individual to patronize a particular dispensary, laboratory or practitioner, or to purchase particular medical marijuana products.

*Applicant*—Depending on the context the term may mean any of the following:

- (i) A person who wishes to submit or submits an application to the Department for a permit to operate as a grower/processor or dispensary, or both, under the act and this part.
- (ii) A patient or a caregiver who submits an identification card application to the Department.
  - (A) The term includes a legal guardian or a parent who submits an application on behalf of a patient.
  - (B) The term does not include an individual under 21 years of age unless the Department has determined under section 507(a) of the act (35 P.S. § 10231.507(a)) that the individual should be permitted to serve as a caregiver.

(C) A person who submits an application to the Department to become an approved laboratory, an ACRC, or a clinical registrant.

*Approved laboratory*—A laboratory that has applied for, and received, the approval of the Department to identify, collect, handle and conduct tests on samples from a grower/processor and test samples from the Department used in the growing and processing of medical marijuana or dispensing of medical marijuana products as required by the act and this part.

*CAS number* – The unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service, a division of the American Chemical Society.

*CBC* – Cannabichromene, CAS number 20675-51-8.

*CBD*—Cannabidiol, CAS number 13956-29-1.

*CBDA* – Cannabidiolic acid, CAS number 1244-58-2.

*CBDV* – Cannabidivarin, CAS number 24274-48-4

*CBG* – Cannabigerol, CAS number 25654-31-3.

*CBN* – Cannabinol, CAS number 521-35-7.

*Cannabinoids* – The chemical compounds that are the active constituents of marijuana.

*Caregiver*—One of the following:

- (i) An individual designated by a patient to obtain on behalf of a patient, and provide to a patient, a medical marijuana product.
- (ii) For a minor patient, an individual who meets the requirements in section 506(2) of the act (35 P.S. § 10231.506(2)).

*Certificate of accreditation*—A document issued by an accreditation body evidencing that a laboratory is in compliance with International Organization for Standardization Standard ISO/IEC 17025 or other standards relevant to the operation of laboratories conducting tests on medical marijuana, medical marijuana products and other items used in the growing and processing of medical marijuana or dispensing of medical marijuana products.

*Certificate of analysis*—A document that confirms that the test performed by an approved laboratory on a harvest batch, harvest lot or process lot meets the testing requirements set forth by the Department.

*Certified medical use*—The acquisition, possession, use or transportation of medical marijuana products by a patient; or the acquisition, possession, delivery, transportation or administration of medical marijuana products by a caregiver, for use as part of the treatment of the patient’s serious medical condition, as authorized in a patient

certification, including enabling the patient to tolerate treatment for the serious medical condition.

*Certified registered nurse practitioner*—The term as defined in section 2 of The Professional Nursing Law (63 P.S. § 212).

*Chain of custody*—The written procedures used by employees of an approved laboratory to record the possession and transfer of samples and test samples from the time the samples and test samples are collected until the test of the sample or test sample is completed.

*Change in control*—The acquisition by a person or group of persons acting in concert of a controlling interest in an applicant or permittee either all at one time or over the span of a 12-consecutive-month period.

*Change in ownership*—The addition or removal of a principal, operator or financial backer or a change in control of a medical marijuana organization after the Department approves an initial permit application or a permit renewal application.

*Clinical registrant*—An entity that:

- (i) Holds a permit as both a grower/processor and a dispensary;
- (ii) Has a contractual relationship with an academic clinical research center

under which the academic clinical research center or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances; and

- (iii) Is approved by the Department as a clinical registrant.

*Continuing care*—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.

*Controlled substance*—A drug, substance or immediate precursor included in Schedules I—V as listed in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).

*Controlling interest*—

- (i) For a publicly traded entity, voting rights that entitle a person to elect or appoint one or more of the members of the board of directors or other governing board or the ownership or beneficial holding of 5% or more of the securities of the publicly traded entity.
- (ii) For a privately held entity, the ownership of any security in the entity.

*D8* – Delta 8 Tetrahydrocannabinol, CAS number 5957-75-5.

*Department*—The Department of Health of the Commonwealth.

*Device*—An object used, intended for use or designed for use in preparing, storing, ingesting, inhaling or otherwise introducing medical marijuana into the human body.

*Disadvantaged business*—The term as defined in 74 Pa.C.S. § 303(b) (relating to diverse business participation).

*Dispensary*—

- (i) A person who holds a permit issued by the Department to dispense medical marijuana products.
- (ii) The term does not include a health care medical marijuana organization as defined under sections 1901—1908 of the act (35 P.S. § § 10231.1901—10231.1908).

*Dispense*—The activity of lawfully providing to a patient or caregiver medical marijuana products in a suitable container that is appropriately labeled for subsequent administration or use pursuant to a patient certification issued by a practitioner.

*Diverse group*—A disadvantaged business, minority-owned business, women-owned business, service- disabled veteran-owned small business or veteran-owned small business that has been certified by a third- party certifying organization.

*Diverse participants*—The term includes the following:

- (i) Individuals from diverse racial, ethnic and cultural backgrounds and communities.
- (ii) Women.
- (iii) Veterans.
- (iv) Individuals with disabilities.

*Diversity plan*—A strategy that promotes or ensures participation by diverse groups in the management and operation of a medical marijuana organization through contracting and employment opportunities.

*Electronic tracking system*—An electronic seed-to-sale system approved by the Department that is utilized by:

- (i) A grower/processor to log, verify and monitor the receipt, use and sale of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products, the funds received by a grower/processor for the sale of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to another medical marijuana organization, the disposal of medical marijuana waste and the recall of defective seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

- (ii) A dispensary to log, verify and monitor the receipt of medical marijuana product from a grower/processor, the verification of the validity of an identification card presented by a patient or caregiver, the dispensing of medical marijuana product to a patient or caregiver, the disposal of medical marijuana waste and the recall of defective medical marijuana products.
- (iii) An approved laboratory to log, verify and monitor the receipt of samples and test samples for testing, the results of tests performed by the approved laboratory, and the disposal of tested and untested samples and test samples.

*Employee*—An individual who is hired for a wage, salary, fee or payment to perform work for an applicant or permittee.

*Excipients*—Solvents, chemicals or materials reported by a medical marijuana organization and approved by the Department for use in the processing of medical marijuana.

*Facility*—A structure and other appurtenances or improvements where a medical marijuana organization grows and processes or dispenses medical marijuana.

*Family or household member*—The term as defined in 23 Pa.C.S. § 6102 (relating to definitions).

*Financial backer*—An investor, mortgagee, bondholder, note holder, or other source of equity, capital or other assets other than a financial institution.

*Financial institution*—A bank, a National banking association, a bank and trust company, a trust company, a savings and loan association, a building and loan association, a mutual savings bank, a credit union or a savings bank.

*Form of medical marijuana*—The characteristics of the medical marijuana recommended or limited for a particular patient, including the method of consumption and any particular dosage, strain, variety and quantity or percentage of medical marijuana or particular active ingredient.

*Fund*—The Medical Marijuana Program Fund established in section 902 of the act (35 P.S. § 10231.902).

*Grower/processor*—

- (i) A person who holds a permit from the Department under the act to grow and process medical marijuana.
- (ii) The term does not include a health care medical marijuana organization as defined under sections 1901—1908 of the act.

*Harvest batch*—A specifically identified quantity of medical marijuana plant that is

uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location, and cured under uniform conditions.

*Harvest lot*—A specifically identified quantity of medical marijuana plant taken from a harvest batch.

*Health care medical marijuana organization*—A vertically integrated health system approved by the Department to dispense medical marijuana or grow and process medical marijuana, or both, in accordance with a research study under sections 1901—1908 of the act.

*Hydroponic nutrient solution*—A mixture of water, minerals and essential nutrients without soil used to grow medical marijuana plants.

*IRB--Institutional review board*--A board, committee, RAC or group designated by an ACRC that reviews and approves the anticipated scope of an approved clinical registrant's research study involving human subjects under the criteria in 45 CFR 46.111 (relating to criteria for IRB approval of research) and 21 CFR 56.111 (relating to criteria for IRB approval of research).

*Identification card*—A document issued under section 501 of the act (35 P.S. § 10231.501) that authorizes a patient or caregiver to have access to medical marijuana products under the act.

*Immature medical marijuana plant*—A rootless, nonflowering part of a medical marijuana plant that is no longer than 12 inches and no wider than 12 inches produced from a cutting, clipping or seedling and that is in a growing container that is no larger than 2 inches wide and 2 inches tall that is sealed on the sides and bottom.

*Immediate family*—The term as defined in 4 Pa.C.S. § 1512(b) (relating to financial and employment interests).

*Industrial hemp*—The plant *Cannabis sativa* L., and any part of the plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3% on a dry-weight basis.

*Initial permit application*—The document submitted to the Department by an applicant that, if approved, grants a permit to an applicant.

*Institution of higher education*--A community college, State-owned institution, State-related institution, or private college or university approved by the Department of Education.

*Laboratory*—A place, establishment or institution within this Commonwealth that has been issued a certificate of accreditation.

*Legal guardian—*

- (i) An individual appointed as a guardian of a patient under the laws of the Commonwealth.
- (ii) The term does not include an individual who has been appointed a guardian only of a patient's property.

*Limited access area—*Any area on a site or within a facility where:

- (i) Immature medical marijuana plants or medical marijuana plants are growing or being processed into medical marijuana.
- (ii) Immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products are being loaded into or out of transport vehicles.
- (iii) Seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products are packaged for sale or stored.
- (iv) Medical marijuana waste is processed, stored or destroyed.
- (v) Surveillance system devices are stored or maintained.

*Marijuana—*

- (i) All parts of the plant *Cannabis sativa* L., whether growing or not, the seeds of that plant and resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin.
- (ii) The term does not include industrial hemp.

- (iii) The term does not include the mature stalks of *Cannabis sativa* L., fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt or derivative, mixture or preparation of the mature stalks.
- (iv) The term does not include synthetic cannabinoids as defined in 35 P.S. § 780-104(1)(vii).

*Medical Board*—Either of the following:

- (i) The State Board of Medicine as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2).
- (ii) The State Board of Osteopathic Medicine as defined in section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

*Medical marijuana*—Marijuana for certified medical use, limited to the following forms:

- (i) Pill.
- (ii) Oil.
- (iii) Topical forms, including gels, creams or ointments.
- (iv) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization.
- (v) Tincture.
- (vi) Liquid.

*Medical marijuana cardholder*—An adult patient or caregiver who possesses a valid identification card.

*Medical marijuana container*—A sealed, traceable, food compliant, tamper resistant, tamper evident container used for the purpose of containment of packaged medical marijuana products being transported from a grower/processor to a medical marijuana organization or an approved laboratory.

*Medical marijuana extract*—A substance obtained by separating cannabinoids from a medical marijuana plant by a mechanical, chemical or other process.

*Medical marijuana organization*—

- (i) A dispensary or a grower/processor.
- (ii) The term does not include a health care medical marijuana organization under sections 1901—1908 of the act.

*Medical marijuana patient authorization letter*—A document issued by the Department under § 1191a.32 (relating to medical marijuana patient authorization letters).

*Medical marijuana plant*—A plant which is greater than 12 vertical inches in height from where the base of the stalk emerges from the growth medium to the tallest point of the plant, or greater than 12 horizontal inches in width from the end of one branch to the end of another branch.

*Medical marijuana product*—The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

*Medical Marijuana Program*—The program authorized under the act and implemented by the Department.

*Medical marijuana waste*—

- (i) Solid, liquid, semi-solid or contained gaseous materials that are generated by a grower/processor or an approved laboratory.
- (ii) The term includes:
  - (A) Unused, surplus, returned, recalled, contaminated or expired medical marijuana.
  - (B) Any medical marijuana plant material that is not used in the growing, harvesting or processing of medical marijuana, including flowers, stems, trim, leaves, seeds, dead medical marijuana plants, dead immature medical marijuana plants, unused medical marijuana plant parts, unused immature medical marijuana plant parts or roots.
  - (C) Spent hydroponic nutrient solution.
  - (D) Unused containers for growing immature medical marijuana plants

or medical marijuana plants or for use in the growing and processing of medical marijuana.

(E) Unused fertilizers and pesticides.

(F) Unused excipients.

(G) Wastewater.

*Medical professional*—A physician, pharmacist, physician assistant or certified registered nurse practitioner employed by a dispensary.

*Minor patient*—A patient who is under 18 years of age.

*Minority-owned business*—The term as defined in 74 Pa.C.S. § 303(b).

*Municipal waste*—The term as defined in section 103 of the Solid Waste Management Act (35 P.S. § 6018.103).

*Municipality*—A county, city, borough, incorporated town or township, or any similar general-purpose unit of government which shall hereafter be created by the General Assembly.

*Nebulization*—The generation of medical marijuana products in the form of fine spray for medicinal inhalation.

*Nutrient*—The essential elements and compounds necessary for the growth, metabolism and development of medical marijuana plants.

*Nutrient practice*—The use by a grower/processor of essential elements and compounds necessary for the growth, metabolism and development of seeds, immature medical marijuana plants or medical marijuana plants.

*Office*—The Department’s Office of Medical Marijuana.

*Operational*—The time at which the Department determines that a medical marijuana organization is ready, willing and able to properly carry on the activity for which a permit has been issued under this part, including the implementation of an electronic tracking system.

*Operator*—An individual who directly oversees or manages the day-to-day business functions for an applicant or permittee and has the ability to direct employee activities onsite and offsite or within a facility for which a permit is sought or has been issued under this part.

*Parent*—The biological, natural or adoptive mother or father of a patient.

*Patient*—An individual who:

- (i) Has a serious medical condition.
- (ii) Has met the requirements for certification under the act.

- (iii) Is a resident of this Commonwealth.

*Patient and caregiver registry*—A list of patients and caregivers established and maintained by the Department.

*Patient certification*—The document issued by a practitioner under § 1181a.27 (relating to issuing patient certifications) certifying that a patient has one or more serious medical conditions.

*Patient consultation*—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.

*Permit*—An authorization issued by the Department to a medical marijuana organization to conduct activities authorized under the act.

*Permittee*—A person who has been issued an authorization to operate as a medical marijuana organization under the act and this part.

*Person*—A natural person, corporation, foundation, organization, business trust, estate, limited liability company, licensed corporation, trust, partnership, limited liability partnership, association or other form of legal business entity.

*Pharmacist*—The term as defined in section 2 of the Pharmacy Act (63 P.S. § 390-2).

*Physician*—The term as defined in section 2 of the Medical Practice Act of 1985 (63 P.S. § 422.2) and section 2 of the Osteopathic Medical Practice Act (63 P.S. § 271.2).

*Physician assistant*—The term as defined in section 2 of the Medical Practice Act of 1985 and section 2 of the Osteopathic Medical Practice Act.

*Practitioner*—A physician who is registered with the Department under section 401 of the act (35 P.S. § 10231.401).

*Practitioner registry*—A list of practitioners established and maintained by the Department.

*Prescription Drug Monitoring Program*—The Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act (35 P.S. §§ 872.1—872.40).

*Principal*—An officer, director or person who directly or beneficially owns securities of an applicant or permittee, or a person who has a controlling interest in an applicant or permittee or who has the ability to elect the majority of the board of directors of an applicant or permittee or otherwise control an applicant or permittee, other than a financial institution.

*Process lot*—Any amount of a medical marijuana product of the same type and processed

using the same medical marijuana extract, standard operating procedures and the same or combination of different harvest lots.

*Processing*—The compounding or conversion of medical marijuana extract by a grower/processor into a medical marijuana product.

*Professional disciplinary action*—A disciplinary proceeding taken by the applicable Medical Board against a practitioner that results in a corrective action or measure.

*Publicly traded company*—A person other than an individual who:

- (i) Has a class or series of securities registered under the Securities Exchange Act of 1934 (15 U.S.C.A. §§ 78a—78pp) or on a foreign stock exchange determined by the Department to have similar listing and reporting requirements to exchanges that are regulated under the Securities Exchange Act of 1934.
- (ii) Is a registered management company under the Investment Company Act of 1940 (15 U.S.C.A. §§ 80a-1—80a-64).
- (iii) Is subject to the reporting obligations imposed by section 15(d) of the Securities Exchange Act of 1934 (15 U.S.C.A. § 780(d)) by reason of having filed a registration statement which has become effective under the Securities Act of 1933 (15 U.S.C.A. §§ 77a—77aa).

*RAC--Research approval committee*--A board, committee or group created or designated

by an ACRC to review and approve the scope and research protocols of a research program proposed by an approved clinical registrant.

*Research*--Any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

*Research contract*--A written agreement between an approved clinical registrant and an ACRC that contains the responsibilities and duties of each party with respect to the research program or research study that the approved clinical registrant and the ACRC intend to conduct under this chapter and under which the ACRC will provide medical advice to the approved clinical registrant regarding, among other areas, patient health and safety, medical applications, and dispensing and management of controlled substances. This term shall include a letter of intent to enter into an agreement for purposes of a clinical registrant application.

*Research program*--Research on the therapeutic or palliative efficacy of medical marijuana limited to the serious medical conditions defined by the act and this part.

*Research project or study*--Any other research on medical marijuana or its effectiveness in treating a medical or psychological condition.

*Research protocol*--A written procedure for conducting a research program or research study that includes all of the following information:

(i) With respect to the investigator:

(A) Name and address.

(B) Institutional affiliation.

(C) Qualifications, including a curriculum vitae and list of publications, if any.

(ii) With respect to the research program or research study:

(A) Title of the research program or research study.

(B) Statement of the purpose.

(C) Type of medical marijuana product involved and the amount needed.

(D) Description of the research to be conducted, including the number and type of medical marijuana product, the dosage, the route and method of administration, and the duration of the research program or research study.

(E) The locations of the dispensaries that will be participating in the research program or research study.

*Sample*—Medical marijuana or medical marijuana products collected by an employee of an approved laboratory from a grower/processor facility for testing by the laboratory.

*Security*—The term as defined in section 102(t) of the Pennsylvania Securities Act of 1972 (70 P.S. § 1- 102(t)).

*Serious medical condition*—Any of the following conditions:

(i) Cancer, including remission therapy.

- (ii) Positive status for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome.
- (iii) Amyotrophic lateral sclerosis.
- (iv) Parkinson's disease.
- (v) Multiple sclerosis.
- (vi) Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies.
- (vii) Epilepsy.
- (viii) Inflammatory bowel disease.
- (ix) Neuropathies.
- (x) Huntington's disease.
- (xi) Crohn's disease.
- (xii) Post-traumatic stress disorder.
- (xiii) Intractable seizures.
- (xiv) Glaucoma.
- (xv) Sickle cell anemia.
- (xvi) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.
- (xvii) Autism.

- (xviii) Neurodegenerative diseases.
- (ixx) Terminal illness.
- (xx) Dyskinetic and spastic movement disorders.
- (xxi) Opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.
- (xxii) Anxiety disorders
- (xxiii) Tourette's Syndrome
- (xxiv) Any other condition recommended by the Medical Marijuana Advisory Board and approved by the Secretary.

*Service-disabled*—The term as defined in 51 Pa.C.S. § 9601 (relating to definitions).

*Service-disabled veteran-owned small business*—The term as defined in 51 Pa.C.S. § 9601.

*Site*—The total area contained within the property line boundaries in which a facility is operated by a medical marijuana organization.

*Spent hydroponic nutrient solution*—Hydroponic nutrient solution that has been used and can no longer serve the purpose for which it was produced.

*THC*—Delta-9 Tetrahydrocannabinol, CAS number 1972-08-3.

*THCA* – Tetrahydrocannabinolic acid, CAS number 23978-85-0.

*THCV* – Tetrahydrocannabivarin, CAS number 31262-37-0.

*Terminal illness*—A condition or disease for which the medical prognosis of life expectancy is approximately 1 year or less if the condition or disease runs its normal course.

*Terpenes* – Naturally occurring hydrocarbons found in essential oil secreted from the marijuana plant.

*Test sample*—An amount of medical marijuana, medical marijuana products or an amount of soil, growing medium, water or solvents used to grow or process medical marijuana, dust or other particles obtained from the swab of a counter or equipment used in the growing or processing of medical marijuana, or other item used in the growing or processing of medical marijuana in a grower/processor facility taken by an employee of an approved laboratory or an agent of the Department at the request of the Department from a grower/processor facility and provided to an approved laboratory for testing.

*Third-party certifying organization*—The term as defined in 74 Pa.C.S. § 303(b).

*Transport vehicle*—A vehicle that meets the requirements of the act and is used to

transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products between medical marijuana organizations or between medical marijuana organizations and an approved laboratory.

*Unit*—The weight or volume of total usable medical marijuana products, calculated in metric units.

*Vaporization*—The generation of medical marijuana products in the form of vapor for medicinal inhalation.

*Veteran*—The term as defined in 51 Pa.C.S. § 9601.

*Veteran-owned small business*—The term as defined in 51 Pa.C.S. § 9601.

*Women-owned business*—The term as defined in 74 Pa.C.S. § 303(b).

§ 1141a.22. Records subject to disclosure; confidentiality.

- (a) The following records are public records and are subject to disclosure under the Right-to-Know Law (65 P.S. § 67.101—67.3104):
- (1) An application submitted under the act, except to the extent that the application contains any of the information listed in subsection (b).
  - (2) The name, business address and medical credentials of a practitioner.
  - (3) Information regarding penalties or other disciplinary actions taken against

a permittee by the Department for a violation of the act.

- (b) The following information is considered confidential, is not subject to the Right-to-Know Law and will not otherwise be released to a person unless pursuant to court order:
- (1) Information in the possession of the Department or any of its contractors regarding a practitioner's registration information that is not listed as a public record under subsection (a).
  - (2) The name or other personal identifying information of a patient or caregiver who applies for or is issued an identification card.
  - (3) Individual identifying information concerning a patient or caregiver, or both.
  - (4) A patient certification issued by a practitioner.
  - (5) Any information on an identification card.
  - (6) Information provided by the Pennsylvania State Police regarding a caregiver, including criminal history record information, as set forth in § 1141a.31 (relating to background checks).
  - (7) Information regarding a patient's serious medical condition.
  - (8) Other information regarding a patient, caregiver, practitioner or medical marijuana organization not listed in subsection (a) that falls within an exception to the Right-to-Know Law, or is otherwise considered to be confidential proprietary information by other law.
  - (9) Information regarding the physical features of, and security measures installed in, a facility.

- (10) Information maintained in the electronic tracking system of a grower/processor, an approved laboratory and a dispensary.
  - (11) Any information that would identify persons reviewing permit applications, including a reviewer's name, individual permit application reviews and notes.
  - (12) Information relating to an applicant's diversity plan that is marked confidential proprietary or trade secret.
- (c) An applicant shall mark confidential proprietary information as confidential proprietary or trade secret information, as defined in section 102 of the Right-to-Know Law (65 P.S. § 67.102), prior to submission of a permit application to the Department.
  - (d) 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.
  - (e) An applicant is responsible for defending its own redactions to protect confidential proprietary or trade secrets in any administrative or court proceeding, including any appeals. Any information not adequately defended by the applicant may result in full disclosure of the information in un-redacted form.
  - (f) 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 IRB to ensure that the use of the data is limited to the specified research purposes.

- (g) Notwithstanding subsection (b), in accordance with Section 301(a)(11) of the act, the Department may collaborate with other Commonwealth agencies as necessary to carry out the provisions of the act and this part. Collaboration shall include the sharing of information, including information deemed confidential under the act and this part, with any other agency, when needed to investigate a potential violation of the act or this part. Any information shared pursuant to this section shall remain confidential and may not be disclosed except for investigatory or enforcement purposes.

§ 1141a.23. Limitation on number of permits.

Except as provided in section 2002 of the act (35 P.S. § 10231.2002), the following limitations apply regarding the number of permits to be issued under this part:

- (1) The Department will not initially issue permits to more than 25 applicants for grower/processor permits. The following apply:
  - (i) The Department will not issue more than one individual grower/processor permit to one person.
  - (ii) The Department will not issue an individual dispensary permit to more than five individual grower/processors.
- (2) The Department will not initially issue permits to more than 50 applicants for dispensary permits. The following apply:
  - (i) The Department will not issue more than five individual dispensary permits to one person.
  - (ii) A dispensary permit may be used to provide medical marijuana at

no more than three separate locations as approved by the Department.

- (3) In accordance with section 1201(j)(5)(iv) of the act (35 P.S. § 10231.1201(j)(5)(iv)), the Department may issue permits in addition to those in paragraphs (1) and (2) if necessary as the Medical Marijuana Program expands, including to comply with an order of court. No more than 20% of the total number of growers/processors may also be issued permits as dispensaries.

§ 1141a.24. Medical marijuana regions.

- (a) The Department will issue permits to applicants in each of six medical marijuana regions. The six medical marijuana regions are as follows:
  - (1) *Region 1*—The geographical region comprised of the counties of the Department’s Southeast District, which includes Berks, Bucks, Chester, Delaware, Lancaster, Montgomery, Philadelphia and Schuylkill.
  - (2) *Region 2*—The geographical region comprised of the counties of the Department’s Northeast District, which includes Carbon, Lackawanna, Lehigh, Luzerne, Monroe, Northampton, Pike, Susquehanna, Wayne and Wyoming.
  - (3) *Region 3*—The geographical region comprised of the counties of the Department’s Southcentral District, which includes Adams, Bedford, Blair, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lebanon, Mifflin, Perry and York.

- (4) *Region 4*—The geographical region comprised of the counties of the Department’s Northcentral District, which includes Bradford, Centre, Clinton, Columbia, Lycoming, Montour, Northumberland, Potter, Snyder, Sullivan, Tioga and Union.
  - (5) *Region 5*—The geographical region comprised of the counties of the Department’s Southwest District, which includes Allegheny, Armstrong, Beaver, Butler, Cambria, Fayette, Greene, Indiana, Somerset, Washington and Westmoreland.
  - (6) *Region 6*—The geographical region comprised of the counties of the Department’s Northwest District, which includes Cameron, Clarion, Clearfield, Crawford, Elk, Erie, Forest, Jefferson, Lawrence, McKean, Mercer, Venango and Warren.
- (b) The Department will consider the following factors about each region in its determination to grant or deny an initial permit to an applicant:
- (1) Regional population.
  - (2) The number of patients suffering from a serious medical condition.
  - (3) The types of serious medical conditions in the region.
  - (4) Access to public transportation.
  - (5) The health care needs of rural and urban areas.
  - (6) Areas with recognized need for economic development.
- (c) The publication of this section in the *Pennsylvania Bulletin* is deemed to be the notice of the establishment of the regions required under section 604 of the act (35 P.S. § 10231.604). The Department may change the number or boundaries of the

regions every two years upon publication of notice of the adjustment in the *Pennsylvania Bulletin*.

§ 1141a.25. General requirements for permits.

- (a) The Department may issue a permit to an applicant only for the specific location identified in the applicant's application, by name and address. A permit will specify that the applicant is authorized to begin the process necessary to become operational. A permit is only valid for the person named in the permit and only for the location specified in the permit.
- (b) The medical marijuana organization shall conspicuously post its permit in a location within its facility that is visible to the Department or its authorized agents and law enforcement.
- (c) A permit will not be issued to a medical marijuana organization for use in a personal residence or any other location where the Department or its authorized agents or law enforcement would have limited access.
- (d) A permit will not be issued to a medical marijuana organization for a site or facility located on lands owned by the United States or the Commonwealth.
- (e) A permit is valid for one year from the date of issuance.

§ 1141a.26. Privilege and nontransferability.

- (a) The issuance or renewal of a permit to a medical marijuana organization is a revocable privilege.
- (b) A permit issued under this part is not transferable to any person or any location.

§ 1141a.27. General requirements for application.

- (a) The types of applications to be submitted to the Department under this part include:
  - (1) An initial permit application.
  - (2) A permit renewal application.
  - (3) An application for change in ownership of a medical marijuana organization.
  - (4) An application for approval of a change of location of an operational facility.
  - (5) An application for approval of alteration of a facility.
  - (6) An application for additional dispensary locations.
  - (7) An application for approval of a laboratory.
- (b) 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.
- (c) An application for an initial permit or for a renewal permit is not complete and will be rejected by the Department unless:
  - (1) The payment of the applicable application fee in § 1141a.28 (relating to fees) is submitted with the application.
  - (2) The applicant and its principals and other persons affiliated with the applicant identified by the Department are current in all tax obligations

due and owing to the Commonwealth. An applicant, as part of the application, shall provide tax clearance certificates issued by the Department of Revenue and the Department of Labor and Industry for the applicant and its principals and other persons affiliated with the applicant identified by the Department verifying that the applicant does not have outstanding tax obligations to the Commonwealth. The Department may consider the application to be complete if the applicant states on a form prescribed by the Department of Revenue or the Department of Labor and Industry that tax clearance certificates have been requested at the time the application was submitted to the Department.

- (3) All required information for each section of the application, including attachments and any supplemental information required by the Department, is submitted to the Department.
  - (4) Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.
- (d) An application for an initial permit that is incomplete will be rejected by the Department.
- (e) An application submitted under this part must contain the following statement signed by the applicant:
- A false statement made in this application is punishable under the applicable provisions of 18 Pa.C.S. Ch. 49 (relating to falsification and intimidation).

§ 1141a.28. Fees.

(a) An applicant for an initial grower/processor permit or renewal permit shall pay the following fees by certified or cashier's check or money order to the

Department:

(1) Initial permit application fee—\$10,000. The initial permit application fee shall be submitted with the initial permit application and is nonrefundable, except as provided in § 1141a.29(a)(3) (relating to initial permit application).

(2) Initial permit fee—\$200,000. The initial permit fee shall be submitted with the initial permit application and will be refunded if the initial permit is not granted or the application is rejected.

(3) Permit renewal fee—\$10,000. The permit renewal fee shall be submitted with a renewal application and will be refunded if the renewal permit is not granted.

(4) An initial permit fee refund will be issued to the business named by the applicant in the permit application, in care of the primary contact provided by the applicant and mailed to the primary contact's mailing address provided by the applicant.

(b) An applicant for an initial dispensary permit or renewal permit shall pay the following fees by certified or cashier's check or money order to the Department:

(1) Initial permit application fee—\$5,000. The initial permit application fee shall be submitted with the initial permit application and is nonrefundable, except as provided in § 1141a.29(a)(3) (relating to initial permit

application).

- (2) Initial permit fee—\$30,000 for each dispensary location. The initial permit fee shall be submitted with the initial permit application and will be refunded if the initial permit is not granted or the application is rejected.
  - (3) Permit renewal fee—\$5,000. The permit renewal fee shall be submitted with a renewal application and will be refunded if the renewal permit is not granted.
  - (4) An initial permit fee refund will be issued to the business named by the applicant in the permit application, in care of the primary contact provided by the applicant and mailed to the primary contact's mailing address provided by the applicant.
- (c) A medical marijuana organization shall pay a fee of \$250 by certified or cashier's check or money order to the Department with the submission of the following:
- (1) An application for change in ownership of a medical marijuana organization.
  - (2) An application for approval of a change of location of an operational facility.
  - (3) An application for approval of alteration of a facility.

§ 1141a.29. Initial permit application.

- (a) The Department will publish in the *Pennsylvania Bulletin* notice of initial permit application availability and the time frame during which initial permit applications will be accepted.

- (1) An applicant shall only use the initial permit application form prescribed by the Department on its web site.
  - (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 (relating to records subject to disclosure; confidentiality), by mail in an electronic format that is prescribed by the Department in the initial permit application instructions.
  - (3) An initial permit application received from an applicant after the time frame during which the Department is accepting applications will be rejected by the Department and returned to the applicant without further consideration along with the initial permit application fee and initial permit fee submitted by the applicant with the permit application.
- (b) In addition to the requirements in § 1141a.27 (relating to general requirements for application), the applicant shall provide the Department with the following information in the initial permit application:
- (1) The legal name of the applicant.
  - (2) Certified copies of the applicant's organizational documents, if applicable, and, if the applicant was not organized in this Commonwealth, evidence that it is authorized to conduct business in this Commonwealth.
  - (3) The physical address of the applicant's proposed site and facility, including the following, as applicable:
    - (i) Evidence of the applicant's clear legal title to or option to purchase

- the proposed site and the facility.
- (ii) A fully-executed copy of the applicant's unexpired lease for the proposed site and facility that includes the consent by the property owner to the use by the applicant of that site and facility on the proposed site for, at a minimum, the term of the initial permit.
  - (iii) Other evidence satisfactory to the Department that shows the applicant has the authority to use the proposed site and facility as a site and facility for, at a minimum, the term of the permit.
- (4) Evidence that the applicant is or will be in compliance with the municipality's zoning requirements.
- (5) The following apply to the proposed facility:
- (i) If the facility is in existence at the time the initial permit application is submitted to the Department, the applicant shall submit plans and specifications drawn to scale for the interior of the facility.
  - (ii) If the facility is in existence at the time the initial permit application is submitted to the Department, and the applicant intends to make alterations to the facility, the applicant shall submit renovation plans and specifications for the interior and exterior of the facility to be altered.
  - (iii) If the facility is not in existence at the time the initial permit application is submitted to the Department, the applicant shall submit a plot plan that shows the proposed location of the facility

and an architect's drawing of the facility, including a detailed drawing, to scale, of the interior of the facility.

- (6) The name, residential address, date of birth, title and short version of a curriculum vitae of each principal, operator, financial backer and employee of the applicant, or of any person holding an interest in the applicant's proposed site or facility, including:
  - (i) A verification of identity that is satisfactory to the Department.
  - (ii) Evidence of good moral character and reputation of each principal, operator, financial backer or employee.
  - (iii) A copy of a criminal history records check for each individual performed in accordance with § 1141a.31 (relating to background checks). This subparagraph does not apply to an applicant who is an owner of securities in a publicly traded company if the Department determines that the owner of the securities is not substantially involved in the activities of the applicant.
  - (iv) An affidavit from each principal, operator or financial backer of the applicant setting forth the following:
    - (A) Any position of management or ownership held during the ten years preceding the filing date of the initial permit application of a controlling interest in any other business in this Commonwealth or any other jurisdiction involving the manufacturing or distribution of medical marijuana, medical marijuana products or a controlled substance.

- (B) Whether the principal, operator or financial backer has been convicted of a criminal offense graded higher than a summary offense in this Commonwealth or the lowest-graded criminal offense in another State or country.
  - (C) Whether the principal, operator or financial backer has been a party in any civil or administrative action under the laws of the Commonwealth or any other state, the United States or a military, territorial or tribal authority relating to the principal, operator or financial backer's profession, occupation or fraudulent practices, including fraudulent billing practices.
  - (D) Whether the principal, operator or financial backer has attempted to obtain a registration, license, permit or other authorization to operate a medical marijuana organization in any jurisdiction by fraud, misrepresentation or the submission of false information.
- (7) If a principal, operator or financial backer is a corporation or limited liability company:
- (i) The names, residential addresses, titles and short version of a curricula vitae of each principal of the corporation or limited liability company.
  - (ii) A certified copy of the filed articles of incorporation of the corporation or filed certificate of organization of the limited

liability company.

(iii) Unless the corporation or limited liability company is a publicly traded company, the names and mailing addresses of all persons owning securities in the corporation or membership interests in the limited liability company.

(8) If a principal, operator or financial backer is a general partnership, limited partnership, limited liability partnership or limited liability limited partnership:

(i) The names, residential addresses, titles and short version of a curricula vitae of each partner and general partner of a general partnership, limited partnership, limited liability partnership or limited liability limited partnership, and if any of the partners is a corporation or a limited liability company, the names, residential addresses, titles and short version of a curricula vitae of each principal of that corporation or limited liability company.

(ii) A certified copy of its filed certificate of limited partnership or other formation document, if applicable.

(iii) A certified copy of its partnership agreement.

(iv) Unless the entity is a publicly traded company, the names and mailing addresses of each of its partners.

(9) Evidence that the applicant is responsible and capable of successfully establishing and operating a facility, including the following:

(i) Demonstrated experience, if any, running a for-profit or nonprofit

- organization or other business within this Commonwealth or any other jurisdiction and the nature of the business conducted by the organization.
- (ii) History relating to a similar license, permit or other authorization in other jurisdictions, including provisional licenses, suspensions, revocations or disciplinary actions, including civil monetary penalties or warnings.
  - (iii) History of response to sanctions, disciplinary actions or civil monetary penalties imposed relating to any similar license, permit or other authorization in another jurisdiction, and the plans of correction or other responses made to those actions.
  - (iv) Evidence that the applicant and its principals and other persons affiliated with the applicant identified by the Department is in compliance with all the laws of the Commonwealth regarding the payment of State taxes as shown on the tax clearance certificates issued by the Department of Revenue and the Department of Labor and Industry under § 1141a.27 (relating to general requirements for application).
  - (v) A statement that the applicant shall provide evidence of workers' compensation insurance if the applicant is issued a permit and the facility is determined to be operational by the Department.
- (10) A description of the duties, responsibilities and roles of each principal, operator, financial backer and employee.

- (11) A timetable outlining the steps the applicant will take to become operational.
- (12) A summary of the intended plan of operation that describes, at a minimum, how the applicant's proposed business operations will comply with the act and this part relating to:
  - (i) Security.
  - (ii) Employee qualifications and training.
  - (iii) Transportation of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
  - (iv) Storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
  - (v) With respect to an application for a grower/processor permit, labeling of medical marijuana products.
  - (vi) Inventory management.
  - (vii) With respect to a grower/processor's facility, nutrient practice.
  - (viii) With respect to a grower/processor's facility, quality control and testing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products for potential contamination.
  - (ix) Recordkeeping.
  - (x) Preventing unlawful diversion of seeds, immature medical

marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

- (xi) With respect to a grower/processor's facility, growing of medical marijuana, including a detailed summary of policies and procedures for its growth.
  - (xii) Establishment, implementation and monitoring of diversity goals under § 1141a.32 (relating to diversity goals).
- (13) The relevant financial information in § 1141a.30 (relating to capital requirements).
- (14) Statements that:
- (i) The applicant and each principal, operator, financial backer and employee are of good moral character.
  - (ii) The applicant possesses the ability to obtain in an expeditious manner the right to use the proposed site and facility, including equipment, to properly perform the activity described in the initial permit application.
  - (iii) The grower/processor permit applicant is able to continuously maintain effective security, surveillance and accounting control measures to prevent diversion, abuse and other illegal conduct regarding seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products. The dispensary permit applicant is able to continuously maintain effective security, surveillance and accounting control

measures to prevent diversion, abuse and other illegal conduct regarding medical marijuana products.

- (iv) The applicant is able to continuously comply with all applicable laws of the Commonwealth, the act, this part, and the terms and conditions of the initial permit.
- (15) The applicant shall provide the Department with releases sufficient to obtain information from a governmental agency, financial institutions, an employer or any other person. Failure to provide these releases will result in the rejection of the initial permit application.
- (16) Other information required by the Department.
- (c) If the Department determines that an initial permit application is complete but lacking sufficient information upon which to make a determination, the Department may notify the applicant in writing of the factors that require additional information and documentation. An applicant has 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. An applicant's failure to provide the requested information to the Department by the deadline may be grounds for denial of the issuance of a permit. Nothing in this subsection requires the Department to request additional or supplemental information from an applicant.
- (d) At the discretion of the Department, the Department may extend the deadline in subsection (c) for up to an additional 15 days.
- (e) The Department may conduct an inspection to determine the appropriateness of a proposed site and facility, the applicant's operational status, the applicant's

compliance with the laws and regulations of the Commonwealth, the municipality's zoning requirements relating to the applicant's proposed site and facility, if applicable, and its use as outlined in the permit application. The Department may do the following:

- (1) Interview principals, operators, financial backers and employees, including physicians, pharmacists, physician assistants and certified registered nurse practitioners, engaged and to be engaged in the applicant's operations for the purpose of verifying the information contained in the initial permit application.
- (2) Inspect transport vehicles that are or will be utilized in the transportation of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to a facility or an approved laboratory.

§ 1141a.30. Capital requirements.

- (a) An applicant for a grower/processor permit shall provide an affidavit that the applicant has at least \$2 million in capital, \$500,000 of which is on deposit with one or more financial institutions.
- (b) An applicant for a dispensary permit shall provide an affidavit that the applicant has at least \$150,000 on deposit with one or more financial institutions.
- (c) The affidavit will be in a form prescribed by the Department.
- (d) An applicant shall submit with the initial permit application a signed release allowing the Department to contact each financial institution listed in the

application to verify the requirements of subsection (a) or (b).

§ 1141a.31. Background checks.

- (a) To provide the criminal history record check required under § 1141a.29 (relating to initial permit application), an applicant shall submit fingerprints of its principals, financial backers, operators and employees to the Pennsylvania State Police. The Pennsylvania State Police or its authorized agent will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the individuals whose fingerprints have been submitted and obtaining a current record of criminal arrests and convictions.
- (b) The Department may only use criminal history background check information obtained under this section to determine the character, fitness and suitability to serve in the designated capacity of the principal, financial backer, operator and employee.
- (c) This section does not apply to an owner of securities in a publicly traded company except where the owner holds 5% or more of the company's securities or the owner has voting rights to elect or appoint one or more members of the board of directors or other governing board.
- (d) 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.

§ 1141a.32. Diversity goals.

- (a) In accordance with section 615 of the act (35 P.S. § 10231.615), this section establishes the procedures for promoting and ensuring the involvement of diverse participants and diverse groups in the activities permitted by the act and this part.
- (b) In furtherance of the policy in section 615 of the act, the Department will:
  - (1) Allocate appropriate staff of the Department to assist medical marijuana organizations in fostering the involvement of diverse participants and diverse groups in their operations.
  - (2) Provide enhanced publicity of permitting opportunities and information to assist diverse participants and diverse groups in learning how to apply for permits to be issued under the act and this part.
  - (3) Compile, maintain and make available to medical marijuana organizations lists of diverse participants and diverse groups for the purpose of encouraging medical marijuana organizations to provide employment and contracting opportunities consistent with the act.
- (c) Each medical marijuana organization shall include in its permit application a diversity plan that establishes a goal of equal opportunity and access in employment and contracting by the medical marijuana organization. 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 of section 615(a) of the act.
- (d) A medical marijuana organization may demonstrate achievement of its diversity

goals by employing diverse participants and transacting business with diverse groups.

- (e) The list of diverse groups that are verified by the Department of General Services, Bureau of Diversity, Inclusion and Small Business Opportunities may be used by a medical marijuana organization to establish the eligibility of a diverse group for purposes of this section.
- (f) As part of each application to renew a permit submitted to the Department, a medical marijuana organization shall include information of its efforts to meet the diversity goals of the act and the effectiveness of its diversity plan. The report must include information regarding the following, as applicable:
  - (1) Representation of diverse participants in the medical marijuana organization's workforce.
  - (2) Efforts to reach out to and recruit diverse participants for employment, including for executive and managerial positions.
  - (3) Employee retention efforts.
  - (4) A list of all contracts entered into or transactions conducted by the medical marijuana organization for goods or services with diverse groups.
- (g) A medical marijuana organization may request that any proprietary information submitted to the Department under this section be treated as confidential proprietary information and shall clearly mark this information as confidential proprietary information or trade secret under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104) as set forth in § 1141a.22 (relating to records subject to disclosure; confidentiality).

- (h) 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 to improve its efforts to encourage and promote participation by diverse participants and diverse groups to comply with the diversity goals of the act. The Department may consult with the Department of General Services, Bureau of Diversity, Inclusion and Small Business Opportunities in the review of diversity plans and the reports submitted by medical marijuana organizations under this section.

§ 1141a.33. Review of initial permit applications.

- (a) The Department will review initial permit applications submitted by applicants according to the criteria in section 603(a.1) of the act (35 P.S. § 10231.603(a.1)) and the factors in § 1141a.24(b) (relating to medical marijuana regions).
- (b) The Department will publish the number of permits to be issued and the location of each permit in the *Pennsylvania Bulletin* before the initial permit applications are made available for submission.

§ 1141a.34. Denial of a permit.

The Department may deny the issuance of a permit for any of the following reasons:

- (1) Failure or refusal to submit information or documentation requested by the Department during the review process. Nothing in this paragraph requires the Department to request additional or supplemental information from an applicant.

- (2) Misrepresentation by an applicant of fact, or failure to disclose a material fact to the Department during the review process.
- (3) The results of the criminal history record check received by the Department under § 1141a.31 (relating to background checks) for a principal, financial backer, operator or employee of the applicant indicates that the individual has been convicted of a criminal offense relating to the sale or possession of illegal drugs, narcotics or controlled substances and, following notification by the Department, the applicant fails or refuses to provide the Department with evidence satisfactory to the Department that the individual is no longer associated with the applicant in this capacity.
- (4) Failure to meet the capital funding requirements identified in an affidavit by the applicant or a determination by the Department that the capital funding identified by the applicant is unverifiable.
- (5) The applicant denies the Department or its authorized agents access to any place where a permitted activity is proposed to take place or fails to produce any book, paper, record, document, data or other information when requested by the Department.
- (6) The applicant's medical marijuana license, permit or other authorization in another state or jurisdiction was, is or has been suspended or revoked or the applicant was otherwise disciplined.
- (7) The applicant's plan of operation does not demonstrate, to the satisfaction of the Department, that the applicant is qualified for a permit.
- (8) The Department determines, in its sole discretion, that the applicant has

not met the criteria under § 1141a.33 (relating to review of initial permit applications).

- (9) The Department determines, in its sole discretion, that the issuance of the permit will not be in the best interest of the welfare, health or safety of the citizens of this Commonwealth.

§ 1141a.35. Notice of denial.

- (a) The Department will provide written notice of denial to an applicant.
- (b) The applicant may appeal a notice of denial under 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure).

§ 1141a.36. Permit renewal applications.

- (a) A medical marijuana organization wishing to renew its permit shall submit to the Department a permit renewal application not more than 6 months, nor less than 4 months, prior to the current permit's expiration.
- (b) A medical marijuana organization shall submit the applicable fee in § 1141a.28 (relating to fees) with the permit renewal application.
- (c) A medical marijuana organization shall include the following in the permit renewal application:
  - (1) Information regarding any charge, or any initiated, pending or concluded investigation, during the period of the initial permit or prior renewal

period, by any governmental or administrative agency with respect to:

- (i) Any incident involving the theft, loss or possible diversion of medical marijuana by the medical marijuana organization or from the medical marijuana organization's facility.
  - (ii) Compliance by the medical marijuana organization with the laws of the Commonwealth with respect to any substance in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).
- (2) Information concerning the medical marijuana organization's ability to carry on the activity for which the permit was issued, including medical marijuana product shortages or wait lists occurring during the 12 months prior to the date the renewal permit application was submitted.
- (3) The medical marijuana organization's history of compliance with the act and this part.
- (d) If the Department determines that a permit renewal application is complete but lacking sufficient information upon which to make a determination, the Department will notify the medical marijuana organization in writing of the factors that require additional information and documentation. The medical marijuana organization shall have 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. A medical marijuana organization's failure to provide the requested information to the Department by the deadline may be grounds for denial of the permit renewal application. Nothing in this subsection requires the Department to request

additional or supplemental information from an applicant.

- (e) The Department may conduct an onsite inspection of the medical marijuana organization's site and facility to determine an applicant's continuing compliance with the act and this part.

§ 1141a.37. Denial of renewal of a permit.

- (a) The Department will deny the renewal of a permit if the Department determines:
  - (1) The medical marijuana organization has not or is unlikely to be able to continuously maintain effective control against diversion of medical marijuana at its facility.
  - (2) The medical marijuana organization falsified any part of the permit renewal application or any other application submitted to the Department under this part.
  - (3) The medical marijuana organization is unlikely to comply with all Commonwealth and local laws applicable to the activities in which it may engage under the permit, if renewed.
- (b) An existing permit is immediately invalid upon expiration if the medical marijuana organization has not filed a permit renewal application in accordance with § 1141a.36 (relating to permit renewal applications) and remitted the required fees in accordance with § 1141a.28 (relating to fees).
- (c) Except as provided in subsection (e), a medical marijuana organization may not operate if its permit is not renewed prior to expiration.
- (d) If the Department denies renewal of the permit or if the medical marijuana

organization fails to submit a permit renewal application and permit renewal fee as required under § 1141a.28, the medical marijuana organization shall do the following upon the expiration of the permit:

- (1) Cease all operations authorized by the permit.
  - (2) In the case of a grower/processor, dispose of any remaining seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, plant matter or any growing equipment as set forth in § 1151a.40 (relating to management and disposal of medical marijuana waste).
  - (3) In the case of a dispensary, return the medical marijuana products to the grower/processor where the medical marijuana products originated.
- (e) If a medical marijuana organization submits a permit renewal application and permit renewal fee to the Department as required under § 1141a.28, the Department may administratively extend the existing permit from the date the existing permit expires until the Department can complete its permit renewal application review.

§ 1141a.38. Duty to report.

- (a) During the application process, or at any time during the permit period if a permit is issued, an applicant or medical marijuana organization shall notify the Department:
- (1) In writing of any change in facts or circumstances reflected in the initial permit application or any permit renewal application submitted to the

Department, or any newly discovered or occurring fact or circumstance which would have been included in the application if known at the time the application was submitted.

- (2) In writing of any proposed modification of its plan of operation at least 30 days prior to the proposed modification.
  - (3) Immediately upon becoming aware, and State and local law enforcement immediately upon becoming aware, of any adverse loss from a facility operated by the medical marijuana organization or any vehicle transporting seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to or from a facility operated by the medical marijuana organization.
- (b) If the change in information involves a change in control of the medical marijuana organization, the medical marijuana organization shall surrender its existing permit to the Department, unless the medical marijuana organization submits an application for change in ownership of a medical marijuana organization in accordance with § 1141a.39 (relating to application for change in ownership of a medical marijuana organization).
- (c) If the change in information involves a change in any of the activities on the medical marijuana organization site, including any of the following, the medical marijuana organization shall surrender its existing permit to the Department and take action as required under § 1141a.43 (relating to closure of a facility):
- (1) Discontinuance of operations.
  - (2) Removal of all seeds, immature medical marijuana plants, medical

marijuana plants, medical marijuana and medical marijuana products from the sites and locations by State or Federal authority.

§ 1141a.39. Application for change in ownership of a medical marijuana organization.

- (a) 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, to the Department together with the fee required under § 1141a.28 (relating to fees).
- (b) A medical marijuana organization's application for change in ownership will not be considered complete by the Department until all portions of the application are completed and the appropriate application fee under § 1141a.28 is submitted.
- (c) For each individual that is part of the proposed change in ownership, the medical marijuana organization shall include all of the information required under § 1141a.29 (relating to initial permit application) for the individuals listed in those capacities in the medical marijuana organization's initial permit application or any previously submitted permit renewal application.
- (d) A change in ownership of a medical marijuana organization that occurs without the Department's knowledge and written approval of all individuals affiliating with the medical marijuana organization is a violation of the act and this part.

§ 1141a.40. Application for approval of a change in location of an operational facility.

- (a) A medical marijuana organization wishing to change the location of an operational facility shall submit an application for approval of a change in location to the Department together with the fee required under § 1141a.28 (relating to fees).
- (b) A change in location of an operational facility may not occur until the Department approves the change, in writing, under this section.
- (c) The medical marijuana organization shall submit an application for approval of a change in location on a form prescribed by the Department.
- (d) An application for approval of a change in location must include the reason for requesting the change and other information about the new location as the Department may require.
- (e) The Department will issue a new permit to the medical marijuana organization for the new location if the request is approved.
- (f) Within 180 days of the issuance by the Department of a new permit under subsection (e), the medical marijuana organization shall change the location of its operation to the new location designated in the new permit. Simultaneously with the completion of the move, the medical marijuana organization shall cease to operate at the former location and surrender its existing permit to the Department.  
The following apply:
  - (1) At no time may a medical marijuana organization operate or exercise any of the privileges granted under the permit in both locations.
  - (2) At the discretion of the Department, the Department may extend the 180-day deadline for relocation for up to an additional 90 days.

- (3) Once the new facility is determined to be operational by the Department, the medical marijuana organization may resume operations under the new permit at the new location.
- (g) The Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued.

§ 1141a.41. Application for approval of alteration of a facility.

- (a) Except as provided in subsection (b), after the issuance of a permit, a medical marijuana organization may not make a physical change, alteration or modification to the facility that materially or substantially alters the facility or its usage as listed in the plot plans originally approved by the Department.
- (b) A medical marijuana organization wishing to make any of the following alterations to the facility for which its permit was issued shall submit an application for approval of alteration of a facility, on a form prescribed by the Department, to the Department together with the fee required under § 1141a.28 (relating to fees):
  - (1) An increase or decrease in the total square footage of the facility.
  - (2) The sealing off, creation of or relocation of a common entryway, doorway, passage or other means of public ingress or egress when the common entryway, doorway or passage alters or changes limited access areas.
  - (3) Any of the following made to enhance activities authorized under the permit:
    - (i) Additional electric fixtures or lighting equipment.

- (ii) The lowering of a ceiling.
- (iii) Electrical modifications that require inspection by the local municipality.

§ 1141a.42. Failure to be operational.

- (a) Within 6 months from the date of issuance of a permit, a medical marijuana organization shall notify the Department, on a form prescribed by the Department, that it is operational.
- (b) After the Department receives the notification in subsection (a), the Department will inspect the facility to determine if the medical marijuana organization is operational to the satisfaction of the Department.
- (c) If the medical marijuana organization has not met the operational timetable in the initial permit application to the satisfaction of the Department at the time of the inspection conducted under subsection (b), the Department will notify the medical marijuana organization of the deficiencies. Within 30 days of receiving the Department's notice, the medical marijuana organization shall submit to the Department for approval a plan of correction that sets forth the medical marijuana organization's timeline and a date certain, which may not extend beyond 90 days following the date the Department approves the plan of correction, for correcting the deficiencies.
- (d) If the medical marijuana organization does not comply with its plan of correction as approved by the Department within 90 days following the Department's approval, the Department may revoke or suspend the medical marijuana

organization's permit under § 1141a.47 (relating to general penalties and sanctions).

§ 1141a.43. Closure of a facility.

- (a) A medical marijuana organization shall notify the Department in writing immediately, but in no event less than 60 days prior to the projected date of closure, upon making a determination that it intends to close a facility.
- (b) A medical marijuana organization may not accept or purchase seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments as of the date of notice.
- (c) The notice must be accompanied by the medical marijuana organization's written plan for the facility being closed that must include the following information:
  - (1) The projected date of closure.
  - (2) How it intends to notify in writing, prior to the projected date for closure, any person to which the medical marijuana organization provides seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or medical marijuana services prior to closure.
  - (3) How it intends to dispose of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products or other plant matter projected to still be in the facility at the time of the projected closure in accordance with § 1151a.40 (relating to management

and disposal of medical marijuana waste).

- (4) How it intends to dispose of equipment or medical devices or instruments used by the medical marijuana organization in its operations at the facility.
- (d) A medical marijuana organization may not remove or destroy any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, other plant matter, medical marijuana products, equipment, or medical devices or instruments until the Department has approved its plan for closure submitted under subsection (c) and shall comply with all requirements regarding disposal of medical marijuana in § 1151a.40.
- (e) The Department may enter and inspect the site and facility and the medical marijuana organization's vehicles following receipt of a medical marijuana organization's plan of closure to determine whether to approve the medical marijuana organization's closure plan.
- (f) If the Department approves the medical marijuana organization's plan to close a facility submitted under this section, the medical marijuana organization shall surrender its permit to the Department on or before the date for closure provided in the plan.

§ 1141a.44. Insurance requirements.

- (a) A medical marijuana organization shall obtain and maintain an appropriate amount of insurance coverage that insures the site and facility and equipment used in the operation of the facility. An adequate amount of comprehensive liability insurance covering the medical marijuana organization's activities authorized by

the permit shall begin on the date the initial permit is issued by the Department and continuing for as long as the medical marijuana organization is operating under the permit.

- (b) A medical marijuana organization shall obtain and maintain workers' compensation insurance coverage for employees at the time the medical marijuana organization is determined to be operational by the Department.

§ 1141a.45. Inspection and investigation.

- (a) The Department may conduct announced or unannounced inspections or investigations to determine the medical marijuana organization's compliance with its permit, the act or this part.
- (b) An investigation or inspection may include:
  - (1) Inspection of a medical marijuana organization's site, facility, vehicles, books, records, papers, documents, data, and other physical or electronic information.
  - (2) Questioning of employees, principals, operators, financial backers, authorized agents of, and any other person or entity providing services to the medical marijuana organization.
  - (3) Inspection of a grower/processor facility's equipment, instruments, tools and machinery that are used to grow, process and package medical marijuana, including containers and labels.
- (c) The Department and its authorized agents will have free access to review and, if necessary, make copies of books, records, papers, documents, data, or other

physical or electronic information that relates to the business of the medical marijuana organization, including financial data, sales data, shipping data, pricing data and employee data.

- (d) Failure of a medical marijuana organization to provide the Department and its authorized agents immediate access to any part of a medical marijuana organization's site or facility, requested material, physical or electronic information, or individual as part of an inspection or investigation may result in the imposition of a civil monetary penalty, suspension or revocation of its permit, or an immediate cessation of operations pursuant to a cease and desist order issued by the Department.
- (e) The Department and its authorized agents will have free access to any area within a site or facility that is being used to store seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products for testing purposes and are permitted to collect test samples for testing at an approved laboratory.

§ 1141a.46. Reports.

- (a) A medical marijuana organization shall submit the following reports to the Department, on forms prescribed by the Department, at the end of the first 12-month period following the issuance of a permit, and as of the end of each 3-month period thereafter:
  - (1) In the case of a grower/processor:
    - (i) The number of medical marijuana products sold by the

grower/processor to dispensaries during the period for which the report is being submitted.

(ii) The average price per unit of medical marijuana products sold by the grower/processor to a medical marijuana organization.

(iii) The number or amount of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products sold by the grower/processor to other growers/processors during the period for which the report is being submitted.

(2) In the case of a dispensary:

(i) The number of medical marijuana products purchased by the dispensary during the period for which the report is being submitted.

(ii) The average price per unit of medical marijuana products purchased by the dispensary.

(iii) The average price per unit of an amount of medical marijuana products dispensed to a patient or caregiver by the dispensary and in a unit of measurement as determined by the Department.

(b) The Department will aggregate the information in the reports submitted by medical marijuana organizations under subsection (a) and post the information on the Department's web site.

(c) The Department may require ongoing reporting of operational and financial information in a form and manner prescribed by the Department.

- (d) The Department may require any reports necessary to carry out its responsibilities under the act and this part.

§ 1141a.47. General penalties and sanctions.

- (a) In addition to any other penalty imposed by law for violations of the act or this part, the Department may take one or more of the following actions:
  - (1) Suspend or revoke a permit if any of the following occur:
    - (i) The medical marijuana organization fails to maintain effective control against diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products from a facility operated by it or under its control.
    - (ii) The medical marijuana organization violates a provision of the act or this part, or an order issued under the act or this part.
    - (iii) The medical marijuana organization violates a provision of other State or local laws regarding the operation of its facility.
    - (iv) The medical marijuana organization engages in conduct, or an event occurs, that would have disqualified the medical marijuana organization from being issued a permit or having its permit renewed.
    - (v) The medical marijuana organization submitted falsified information on any application submitted to the Department.
  - (2) Impose a civil penalty of not more than \$10,000 for each violation and an

additional penalty of not more than \$1,000 for each day of a continuing violation. In determining the amount of each penalty, the Department will take the following into consideration:

- (i) The gravity of the violation.
  - (ii) The potential harm resulting from the violation to patients, caregivers or the general public.
  - (iii) The willfulness of the violation.
  - (iv) Previous violations, if any, by the medical marijuana organization being assessed.
  - (v) The economic benefit to the medical marijuana organization being assessed resulting from the violation.
- (3) Suspend or revoke a permit pending the outcome of a hearing if the Department determines that the health, safety or welfare of the public, a patient or a caregiver is at risk.
  - (4) Order the restitution of funds or property unlawfully obtained or retained by a medical marijuana organization.
  - (5) Issue a cease and desist order to immediately restrict the operations of a medical marijuana organization conducted under the permit to protect the public's health, safety and welfare. The following requirements apply:
    - (i) An order may include a requirement that a medical marijuana organization cease or restrict some or all of its operations. In addition, the order may prohibit the use of some or all of the seeds, immature medical marijuana plants, medical marijuana plants,

medical marijuana or medical marijuana products grown, processed or to be sold by the medical marijuana organization.

(ii) An order may be issued by an authorized agent of the Department immediately upon completion of an inspection or investigation if the agent observes or suspects an operational failure or determines that the conditions will likely create a diversion or contamination of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, or a risk to patients or the public.

(iii) An order may include:

(A) An immediate evacuation of the site and facility and the sealing of the entrances to the facility.

(B) A quarantine of some or all of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products found at the facility.

(C) The suspension of the sale or shipment of some or all of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products found at the facility.

(6) Issue a written warning if the Department determines that either:

(i) The public interest will be adequately served under the circumstances by the issuance of the warning.

- (ii) The violation does not threaten the safety or health of a patient, caregiver or the general public, and the medical marijuana organization took immediate action to remedy the violation.
- (b) A person who aids, abets, counsels, induces, procures or causes another person to violate the act or this part, or an order issued under the act or this part, shall also be subject to the civil penalties provided under this section.
- (c) For violations of the act or this part, the Department may require a medical marijuana organization to develop and adhere to a plan of correction approved by the Department. The Department will monitor compliance with the plan of correction. Failure to comply with the plan of correction may result in the Department's taking action under applicable provisions of this section as it deems appropriate.
- (d) The Department's actions under subsections (a) and (b) are subject to 2 Pa.C.S. Chapter 5, Subchapter A (relating to practice and procedure of Commonwealth agencies) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure).

§ 1141a.48. Training.

- (a) As required under the act, the principals and employees of a medical marijuana organization who either have direct contact with patients or caregivers or physically handle seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products shall complete a two-hour training course developed by the Department.

- (1) Principals must successfully complete the course prior to starting initial operation of a facility.
  - (2) Employees must successfully complete the course no later than 90 days after starting employment at the facility.
- (b) The training course required under subsection (a) must provide the following information:
- (1) The provisions of the act and this part relevant to the responsibilities of principals and employees of medical marijuana organizations.
  - (2) Proper handling of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
  - (3) Proper recordkeeping.
  - (4) How to prevent and detect the diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
  - (5) Best practice security procedures.
  - (6) Best practice safety procedures, including responding to the following:
    - (i) A medical emergency.
    - (ii) A fire.
    - (iii) A chemical spill.
    - (iv) A threatening event including:
      - (A) An armed robbery.
      - (B) A burglary.
      - (C) A criminal incident.

- (c) A medical marijuana organization shall retain the attendance records of its principals and employees and make them available for inspection by the Department and its authorized agents upon request.
- (d) The Department will make the two-hour training course available at no cost to the medical marijuana organization, its principals or employees.

§ 1141a.49. Zoning.

- (a) A grower/processor shall meet the identical municipal zoning and land use requirements as other manufacturing, processing and production facilities that are located in the same zoning district.
- (b) A dispensary shall meet the identical municipal zoning and land use requirements as other commercial facilities that are located in the same zoning district.

§ 1141a.50. Advertising by a medical marijuana organization.

- (a) In the advertising and marketing of medical marijuana and medical marijuana products, a medical marijuana organization shall be consistent with the Federal regulations governing prescription drug advertising and marketing in 21 CFR 202.1 (relating to prescription-drug advertisements).
- (b) Promotional, advertising and marketing materials shall be approved by the Department prior to their use.
- (c) 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.

§ 1141a.51. Technical advisories.

The Department may issue technical advisories to assist permittees in complying with the act and this part. Technical advisories do not have the force of law or regulation.

Technical advisories provide guidance on the Department's interpretation of, and how a permittee may maintain compliance with, the act and this part. Notice of the availability of a technical advisory will be published in the *Pennsylvania Bulletin*.

### **CHAPTER 1151 (Reserved)**

#### **§§ 1151.21—1151.45 (Reserved).**

#### **CHAPTER 1151a. GROWERS/PROCESSORS**

§ 1151a.21. Growers/processors generally.

- (a) The qualifications that a grower/processor shall meet to receive a permit are continuing qualifications to maintain the permit.
- (b) In addition to any other requirements in the act or this part, a grower/processor shall comply with the following:
  - (1) A grower/processor may not engage in the business of growing, processing, possessing, selling or offering to sell seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to another medical marijuana organization without first being issued a permit by the Department and without first being determined operational by the Department as required under § 1141a.42 (relating to failure to be operational).
  - (2) A grower/processor may not employ an individual at its facility who is under 18

years of age.

§ 1151a.22. Plans of operation.

- (a) At the time the Department determines a grower/processor to be operational, the grower/processor shall provide the Department with a full and complete plan of operation for review that includes the following:
- (1) Employment policies and procedures.
  - (2) Security policies and protocols including:
    - (i) Staff identification measures.
    - (ii) Monitoring of attendance of staff and individuals requiring access to the facility.
    - (iii) Alarm systems.
    - (iv) Video surveillance.
    - (v) Monitoring and tracking inventory.
    - (vi) Personal security.
  - (3) A process for growing, receiving, processing, packaging, labeling, handling, tracking, transporting, storing, disposing and recalling of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and a process for handling, tracking, transporting, storing and disposing of medical marijuana waste in accordance with applicable laws, rules and regulations.
  - (4) Workplace safety, including conducting necessary safety checks prior to starting the growing and processing of seeds, immature medical marijuana plants, medical

marijuana plants, medical marijuana or medical marijuana products.

- (5) Contamination protocols.
  - (6) Maintenance, cleaning and sanitation of equipment in the facility or on the site, or both.
  - (7) Maintenance and sanitation of the site or the facility, or both.
  - (8) Proper handling and storage of any solvent, gas or other chemical used in growing or processing seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products in accordance with this part and other applicable laws, rules and regulations.
  - (9) Quality control, including regulation of the amount of THC in each process lot, proper labeling and minimization of contamination of medical marijuana or medical marijuana products.
  - (10) Inventory maintenance and reporting procedures.
  - (11) The investigation of complaints and potential adverse events from other medical marijuana organizations, patients, caregivers or practitioners regarding the operation of the grower/processor.
  - (12) A recall plan meeting the requirements of § 1151a.42(d) (relating to complaints about or recall of medical marijuana products).
- (b) A grower/processor shall make the full and complete plan of operation available to the Department upon request and during any inspection of a site or a facility, or both.
- (c) A grower/processor shall comply with its plan of operation.

§ 1151a.23. Grower/processor facilities.

- (a) 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.
- (b) The following areas of a facility must be clearly marked with proper signage:
  - (1) Growing and processing areas. These areas shall be easily observed by the Department and its authorized agents and by law enforcement.
  - (2) Nongrowing and nonprocessing areas.
  - (3) Limited access areas. All areas of ingress and egress to a limited access area must be clearly identified by the posting of a sign which must be not less than 12 inches wide and 12 inches long, composed of letters not less than 1/2 inch in height, which must state:

Do Not Enter—Limited Access Area—Access Limited to Authorized Personnel and Escorted Individuals.
  - (4) Areas that include business offices and reception rooms.
- (c) A facility must have an enclosed secure area out of public sight for the loading and unloading of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products into and from a transport vehicle.

§ 1151a.24. Start-up inventory.

- (a) A grower/processor may obtain seeds from outside of this Commonwealth for the purpose of securing its start-up inventory. 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.

- (b) A grower/processor may not obtain medical marijuana plants from outside of this Commonwealth at any time.
- (c) Within 24 hours of receipt, a grower/processor shall, record in the electronic tracking system each seed that enters the site during the 30-day period under subsection (a).
- (d) Outside any 30-day period permitted under subsection (a), a grower/processor shall only grow medical marijuana plants from seeds or immature medical marijuana plants located physically in its facility, or purchase seeds, immature medical marijuana plants or medical marijuana plants from another grower/processor.

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

- (a) A grower/processor facility may not be open to the general public. When an individual who is not approved to enter the facility requires access to the facility for purposes regarding the growing, processing or testing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, a grower/processor shall require the individual to sign a log, detailing the need for entry, and to wear a temporary identification badge that is visible to others at all times while on the site and in the facility.
- (b) A grower/processor shall require an individual to present government-issued identification that contains a photo to gain access to the site and facility.
- (c) No one under 18 years of age is permitted to enter a grower/processor site or facility.

- (d) A grower/processor shall post a sign in a conspicuous location at each entrance of a site and a facility that states:

THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER.

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

- (1) Require the individual to sign a log and detail the need for entry upon entering and to sign the log when leaving the facility.
- (2) Check the individual's government-issued identification to verify that the name on the identification provided matches the name in the log. A photocopy of the identification must be retained with the log.
- (3) Issue a temporary identification badge with the individual's name and company, if applicable, and a badge number.
- (4) Escort the individual while the individual remains in the facility or on the site.
- (5) Ensure that the individual does not touch any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products located in a limited access area.

- (f) The following apply to the log required under subsections (a) and (e):

- (1) The grower/processor shall maintain the log for four years and make the log available to the Department, State or local law enforcement, and other State or local government officials upon request if necessary to perform the government officials' functions and duties.
- (2) The log must include the full name of each individual granted access to the

facility, the temporary identification badge number, the time of arrival, the time of departure and the purpose of the visit, including the areas of the site and the facility visited and the name of each employee visited.

- (g) This section does not limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government officials, from entering any area of a grower/processor site or facility if necessary to perform the governmental officials' functions and duties that pertain to the act or this part.
- (h) A principal, financial backer, operator or employee of a grower/processor may not receive any type of consideration or compensation for allowing an individual to enter a limited access area.

§ 1151a.26. Security and surveillance.

- (a) A grower/processor shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss.

The security and surveillance systems must include all of the following:

- (1) A professionally-monitored security alarm system that includes the following:
  - (i) Coverage of all facility entrances and exits; rooms with exterior windows, exterior walls, roof hatches or skylights; storage rooms, including those that contain seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products and safes; and the perimeter of the facility.
  - (ii) A silent security alarm system signal, known as a duress alarm, generated by the entry of a designated code into an arming station to signal that the

alarm user is being forced to turn off the system.

- (iii) An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response.
  - (iv) A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress.
  - (v) An electrical, electronic, mechanical or other device capable of being programmed to send a prerecorded voice message requesting dispatch, when activated, over a telephone line, radio or other communication system to a law enforcement, public safety or emergency services agency.
  - (vi) A failure notification system that provides an audible, text or visual notification of any failure in the systems. The failure notification system must provide by telephone, e-mail or text message an alert to a designated security person within the facility within five minutes after the failure.
  - (vii) Smoke and fire alarms.
  - (viii) Auxiliary power sufficient to maintain operation of specified growing and processing areas identified in the grower/processor's plan of operation for at least 48 hours following a power outage.
  - (ix) The ability to ensure all access doors are not solely controlled by an electronic access panel to prevent locks from becoming released during a power outage.
  - (x) Motion detectors.
- (2) A professionally-monitored security and surveillance system that is operational 24

hours per day, seven days per week and records all activity in images capable of clearly revealing facial detail. The security and surveillance system must include all of the following:

- (i) Fixed camera placement that allows for a clear image of all individuals and activities in and around the following:
    - (A) All limited access areas.
    - (B) A room or area containing a security and surveillance system storage device or equipment.
    - (C) Entrances to and exits from a facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.
    - (D) Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage rooms, including those that may contain seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and safes.
    - (E) Twenty feet from the exterior of the perimeter of the facility.
  - (ii) Auxiliary power sufficient to maintain operation for at least 48 hours following a power outage.
  - (iii) The ability to operate under the normal lighting conditions of each area under surveillance.
  - (iv) The ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this subsection.
- (3) The ability to clearly and accurately display the date and time. The date and time

must be synchronized and set correctly and may not significantly obscure the picture.

- (4) The ability to record and store all images captured by each surveillance camera for a minimum of two years in a format that may be easily accessed for investigative purposes. The recordings must be kept:
    - (i) At the facility:
      - (A) In a locked cabinet, closet or other secure place to protect it from tampering or theft.
      - (B) In a limited access area or other room to which access is limited to authorized individuals.
    - (ii) At a secure location other than the location of the facility if approved in writing by the Department.
  - (5) A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under paragraph (4) are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.
- (b) The following requirements regarding the inspection, servicing or alteration of, and the upgrade to, the site's and facility's security and surveillance systems apply:
- (1) The systems shall be inspected and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor.
  - (2) The grower/processor shall conduct maintenance inspections once every month to ensure that any repairs, alterations or upgrades to the security and surveillance systems are made for the proper operation of the systems.

- (3) 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 and shall make the records available to the Department and its authorized agents within two business days following the Department's request or the request of the Department's authorized agents.
- (4) In the event of a mechanical malfunction of the security or surveillance system that a grower/processor anticipates will exceed an eight-hour period, the grower/processor shall notify the Department immediately and, with Department approval, provide alternative security measures that may include closure of the facility.
- (5) The grower/processor shall designate employees to continuously monitor the security and surveillance systems at the facility.
- (6) The following apply regarding records retention:
  - (i) Within two business days following a request, a grower/processor shall provide up to four screen captures of an unaltered copy of a video surveillance recording to the Department or its authorized agents, law enforcement or other Federal, State or local government officials if necessary to perform the governmental officials' functions and duties.
  - (ii) If a grower/processor has been notified in writing by the Department or its authorized agents, law enforcement or other Federal, State or local government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, the grower/processor shall retain an unaltered copy of the recording for four

years or until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the grower/processor that it is not necessary to retain the recording, whichever is longer.

- (c) The grower/processor shall install commercial-grade, nonresidential steel doors and door locks on each room where seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are stored, and on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals.
- (d) At all times, all entrances to and exits from a site and a facility must be securely locked.
- (e) The grower/processor shall have an electronic back-up system for all electronic records.
- (f) The grower/processor shall install lighting to ensure proper surveillance inside and outside of a facility.
- (g) A grower/processor shall limit access to a room in a facility containing security and surveillance monitoring equipment to persons who are essential to maintaining security and surveillance operations; Federal, State and local law enforcement; security and surveillance system service employees; the Department or its authorized agents; and other persons with the prior written approval of the Department. The following requirements apply:
  - (1) A grower/processor shall make available to the Department or the Department's authorized agents, upon request, a current list of authorized employees and service employees or contractors who have access to any security and surveillance areas.
  - (2) A grower/processor facility shall keep security and surveillance rooms locked at

all times and may not use these rooms for any other purpose or function.

§ 1151a.27. Requirements for growing and processing medical marijuana.

- (a) 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.
- (b) A grower/processor shall use a pesticide, fungicide or herbicide listed in Appendix A in a manner that is approved by the Department of Agriculture on the basis of Federal law and regulations.
- (c) A grower/processor shall maintain a log of all actions taken to detect pests or pathogens, and the measures taken for control.
- (d) A grower/processor shall:
  - (1) Use appropriate nutrient practices.
  - (2) Use a fertilizer or hydroponic solution of a type, formulation and at a rate to support healthy growth of plants.
  - (3) Maintain records of the type and amounts of fertilizer and any growth additives used.
- (e) A grower/processor shall perform visual inspections of growing plants and harvested plant material to ensure there is no visible mold, mildew, pests, rot, or grey or black plant material that is greater than an acceptable level as determined by the Department.
- (f) A grower/processor may not use any added substance that alters the dosage level, color, appearance, smell, taste, effect or weight of the medical marijuana unless the

grower/processor has first obtained the prior written approval of the Department.

Excipients must be pharmaceutical grade, unless otherwise approved by the Department.

In determining whether to approve an added substance, the Department will consider:

- (i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under federal guidelines.
  - (ii) Whether the added substance constitutes a known hazard such as, but not limited to, diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.
- (g) A grower/processor shall have a separate and secure area for temporary storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products that are awaiting disposal by the grower/processor.
- (h) A grower/processor may only process the parts of the medical marijuana plant that:
- (1) Are free of seeds and stems.
  - (2) Are free of dirt, sand, debris or other foreign matter.
  - (3) Do not contain a level of mold, rot or other fungus or bacterial diseases higher than the minimum levels acceptable to the Department.
- (i) A grower/processor shall process the medical marijuana plants in a safe and sanitary manner. The following requirements apply:
- (1) Medical marijuana plants, raw material and other product used in the processing of medical marijuana shall be handled on food-grade stainless steel benches or tables.
  - (2) Proper sanitation shall be maintained.

- (3) Proper rodent, bird and pest exclusion practices shall be employed.
- (j) A grower/processor shall install a system to monitor, record and regulate:
  - (1) Temperature.
  - (2) Humidity.
  - (3) Ventilation.
  - (4) Lighting.
  - (5) Water supply.

§ 1151a.28. Forms of medical marijuana.

- (a) A grower/processor may only process medical marijuana for dispensing to a patient or caregiver in the following forms:
  - (1) Pill.
  - (2) Oil.
  - (3) Topical forms, including gel, creams or ointments.
  - (4) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization.
  - (5) Tincture.
  - (6) Liquid.
- (b) A grower/processor may not manufacture, produce or assemble any medical marijuana product, instrument or device without the prior written approval of the Department.

§ 1151a.29. Limit on medical marijuana processing.

- (a) In the form intended to be sold to another medical marijuana organization, medical

marijuana or a medical marijuana product must have a specific concentration of total THC and total CBD and must have a consistent cannabinoid profile. The concentration of the following cannabinoids, at a minimum, shall be reported to the Department by an approved laboratory and include the following on the label (CAS numbers need not be displayed on the label):

- (1) THC.
  - (2) THCA.
  - (3) THCV.
  - (4) CBD.
  - (5) CBDA.
  - (6) CBDV.
  - (7) CBN.
  - (8) CBG.
  - (9) CBC.
  - (10) D8
  - (11) Any other cannabinoid component at > 0.1%.
- (b) Within the first six months after the Department determines the grower/processor to be operational, the grower/processor shall provide the Department with a forecast of the amount of medical marijuana products it projects it will produce and in what form. 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.

§ 1151a.30. Inventory data.

- (a) A grower/processor shall maintain the following inventory data in its electronic tracking system which must include an accounting of and an identifying tracking number for:
  - (1) The number, weight and type of seeds.
  - (2) The number of immature medical marijuana plants.
  - (3) The number of medical marijuana plants.
  - (4) The number of medical marijuana products ready for sale.
  - (5) The number of damaged, defective, expired or contaminated seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products awaiting disposal.
  
- (b) A grower/processor shall establish inventory controls and procedures to conduct inventory reviews and comprehensive inventories at its facility. The following requirements apply:
  - (1) Inventory reviews of medical marijuana plants in the process of growing, and medical marijuana and medical marijuana products that are being stored for future sale shall be conducted monthly.
  - (2) Comprehensive inventories of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products shall be conducted at least annually.
  
- (c) A written or electronic record shall be created and maintained of each inventory conducted under subsection (b) that includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.

§ 1151a.31. Storage requirements.

- (a) A grower/processor shall ensure that a facility has separate and locked limited access areas for storage of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products that are expired, damaged, deteriorated, mislabeled, contaminated, recalled or whose containers or packaging have been opened or breached until the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are destroyed or otherwise disposed of as required under § 1151a.40 (relating to management and disposal of medical marijuana waste).
- (b) A grower/processor facility shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

§ 1151a.32. Equipment, operation and maintenance.

- (a) A grower/processor shall ensure that a facility has a written process in place to maintain the sanitation and operation of equipment that comes into contact with seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to prevent contamination. The grower/processor shall provide a copy of the written process to the Department upon request.
- (b) As part of the written process required under subsection (a), a grower/processor shall:
  - (1) Routinely calibrate, check and inspect the following to ensure accuracy:
    - (i) Automatic, mechanical or electronic equipment.
    - (ii) Scales, balances or other measurement devices used in the

grower/processor's operations.

- (2) Maintain an accurate log recording the following:
  - (i) Maintenance of equipment.
  - (ii) Cleaning of equipment.
  - (iii) Calibration of equipment.

§ 1151a.33. Sanitation and safety in a facility.

(a) A grower/processor shall maintain a facility in a sanitary condition to limit the potential for contamination or adulteration of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown and processed in the facility and any medical marijuana product produced at a facility. The following requirements apply:

- (1) Equipment and surfaces, including floors, counters, walls and ceilings, shall be cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the United States Environmental Protection Agency, in accordance with the instructions printed on the label. Equipment and utensils shall be so designed and of such material and workmanship as to be capable of being adequately cleaned.
- (2) Trash shall be properly removed.
- (3) Floors, walls and ceilings shall be kept in good repair.
- (4) Equipment, counters and surfaces for processing must be food grade quality and may not react adversely with any solvent being used.
- (5) Adequate protection against pests shall be provided through the use of integrated

pest management practices and techniques that identify and manage plant pathogens and pest problems, and the regular disposal of trash to prevent infestation.

- (6) Toxic cleaning compounds, sanitizing agents, solvents used in the growing and processing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, and pesticide chemicals must be labeled and stored in a manner that prevents contamination and that otherwise complies with other applicable laws and regulations.
- (b) An employee working in direct contact with medical marijuana is subject to the restrictions on food handlers in 28 Pa. Code § 27.153 (relating to restrictions on food handlers). An employee shall otherwise conform to sanitary practices while on duty, including the following:
- (1) Maintaining adequate personal hygiene.
  - (2) Wearing proper clothing, including gloves.
  - (3) Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated.
- (c) A grower/processor shall provide adequate and convenient hand-washing facilities furnished with running water at a temperature suitable for sanitizing hands. The following requirements apply:
- (1) A grower/processor shall locate hand-washing facilities in processing areas and where good sanitary practices require employees to wash and sanitize their hands.
  - (2) A grower/processor shall provide effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices.

- (d) A grower/processor shall provide adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.
- (e) A grower/processor shall provide a facility with a water supply sufficient for the facility's operations, which shall be derived from a source that is a public water system, or a nonpublic system that is capable of providing a safe, potable and adequate supply of water to meet the operational needs of the facility.
- (f) A grower/processor shall comply with all other applicable State and local building code requirements.

§ 1151a.34. Packaging and labeling of medical marijuana products.

- (a) A grower/processor shall package and label at its facility each form of medical marijuana products prepared for sale. The original seal of a package may not be broken, except for quality control testing at an approved laboratory, for adverse loss investigations conducted by the Department or by a dispensary that purchased the medical marijuana products.
- (b) A grower/processor shall package the medical marijuana products in a package that minimizes exposure to oxygen and that is:
  - (1) Child-resistant.
  - (2) Tamper-proof or tamper-evident.
  - (3) Opaque.
  - (4) Resealable.
- (c) A grower/processor shall identify each process lot of medical marijuana with a unique identifier.

- (d) 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:
- (1) Be easily readable.
  - (2) Be made of weather-resistant and tamper-resistant materials.
  - (3) Be conspicuously placed on the package.
  - (4) Include the name, address and permit number of the grower/processor.
  - (5) List the form, quantity and weight of medical marijuana included in the package.
  - (6) List the number of individual doses contained within the package, the species and percentage of THC and CBD and other cannabinoids enumerated in section 1151a.29 (relating to limits on medical marijuana processing), and the individual terpenes and corresponding percentages. CAS numbers need not be displayed on the label.
  - (7) Contain an identifier that is unique to a particular harvest batch of medical marijuana, including the number assigned to each harvest lot or process lot in the harvest batch.
  - (8) Include the date the medical marijuana product was packaged.
  - (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.

- (12) List the date of expiration of the medical marijuana product.
  - (13) Include instructions for proper storage of the medical marijuana product in the package.
  - (14) Contain the following warning stating:

This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant's pediatrician.

This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.
  - (15) Contain a warning that the medical marijuana product must be kept in the original container in which it was dispensed.
  - (16) Contain a warning that unauthorized use is unlawful and will subject the purchaser to criminal penalties.
  - (17) Be firmly affixed to the container directly holding medical marijuana and be firmly affixed to outer packaging if used.
  - (18) List THC as the first number when THC and CBD are listed on a label as a ratio.
- (e) Labeling by a grower/processor of any medical marijuana product may not bear:
- (1) Any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available food or beverage product.
  - (2) Any statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.
  - (3) Any seal, flag, crest, coat of arms or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured or

approved for use by any state, county or municipality or any agency thereof.

- (4) Any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

§ 1151a.35. Transportation of medical marijuana.

- (a) A grower/processor may transport and deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical marijuana organization or an approved laboratory in this Commonwealth in accordance with this section. The following requirements apply:
  - (1) Unless otherwise approved by the Department, a grower/processor may deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical marijuana organization or an approved laboratory only between 7 a.m. and 9 p.m.
  - (2) A grower/processor may contract with a third-party contractor for delivery so long as the contractor complies with this section.
  - (3) A grower/processor may not transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to any location outside of this Commonwealth.
  - (4) A grower/processor shall use a global positioning system to ensure safe, efficient delivery of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical marijuana organization or an approved laboratory.
- (b) Vehicles permitted to transport seeds, immature medical marijuana plants, medical

marijuana plants, medical marijuana and medical marijuana products must:

- (1) Be equipped with a secure lockbox or locking cargo area.
  - (2) Have no markings that would either identify or indicate that the vehicle is being used to transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
  - (3) Be capable of being temperature-controlled for perishable seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products, as appropriate.
  - (4) Maintain current State inspection and vehicle registrations.
  - (5) Be insured in an amount that is commercially reasonable and appropriate.
- (c) A transport vehicle must be staffed with a delivery team consisting of at least two individuals and comply with the following:
- (1) At least one delivery team member shall remain with the vehicle at all times that the vehicle contains seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
  - (2) Each delivery team member shall have access to a secure form of communication with the grower/processor, such as a cellular telephone, at all times that the vehicle contains seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
  - (3) Each delivery team member shall carry an identification badge or card at all times and shall, upon demand, produce it to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

- (4) Each delivery team member shall have a valid driver's license.
  - (5) While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
- (d) Seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products stored inside the transport vehicle may not be visible from the outside of the transport vehicle.
- (e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from a grower/processor facility, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are loaded, directly to a medical marijuana organization facility or approved laboratory, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are unloaded, without unnecessary delays.
- Notwithstanding the foregoing, a transport vehicle may make stops at multiple medical marijuana organization facilities or approved laboratories, as appropriate, to deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.
- (f) 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.

- (g) A grower/processor shall notify the Department daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department.
- (h) A transport vehicle is subject to inspection by the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties. A transport vehicle may be stopped and inspected along its delivery route or at any medical marijuana organization or approved laboratory.

§ 1151a.36. Transport manifest.

- (a) A grower/processor shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:
  - (1) The name, address and permit number of the grower/processor and the name of and contact information for a representative of the grower/processor who has direct knowledge of the transport.
  - (2) The name, address and permit number of the medical marijuana organization facility or approved laboratory receiving the delivery and the name of and contact information for a representative of the medical marijuana organization facility or approved laboratory.
  - (3) The quantity, by weight or unit, of each seed, immature medical marijuana plant, medical marijuana plant, medical marijuana harvest batch, harvest lot or process

lot, medical marijuana and medical marijuana product contained in the transport, along with the identification number for each batch or lot.

- (4) The date and approximate time of departure.
  - (5) The date and approximate time of arrival.
  - (6) The transport vehicle's make and model and license plate number.
  - (7) The identification number of each member of the delivery team accompanying the transport.
- (b) When a delivery team delivers seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to multiple medical marijuana organizations or approved laboratories, the transport manifest must correctly reflect the specific seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products in transit. Each recipient shall provide the grower/processor with a printed receipt for the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products received.
- (c) All seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products being transported shall be packaged in shipping containers and labeled in accordance with § 1151 a.34 (relating to packaging and labeling of medical marijuana products).
- (d) A grower/processor shall provide a copy of the transport manifest to the recipient receiving the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products described in the transport manifest. To maintain confidentiality, a grower/processor may prepare separate manifests for each

recipient.

- (e) A grower/processor shall, if requested, provide a copy of the printed transport manifest, and any printed receipts for seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products being transported, to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

§ 1151a.37. Transportation of seeds, immature medical marijuana plants and medical marijuana plants.

- (a) A grower/processor may transport seeds, immature medical marijuana plants and medical marijuana plants within this Commonwealth for the growing and processing of medical marijuana.
- (b) A grower/processor may not transport seeds, immature medical marijuana plants or medical marijuana plants to a location outside of this Commonwealth.
- (c) A grower/processor's authorization to transport seeds, immature medical marijuana plants or medical marijuana plants shall be subject to §§ 1151a.35, 1151a.36 and 1151a.38 (relating to transportation of medical marijuana; transport manifest; and evidence of adverse loss during transport).

§ 1151a.38. Evidence of adverse loss during transport.

- (a) If a grower/processor receiving a delivery of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products from a

medical marijuana organization discovers a discrepancy in the transport manifest that remains unresolved upon delivery, the grower/processor shall refuse acceptance of the delivery and immediately report the discrepancy 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, and to the appropriate law enforcement authorities.

(b) If a grower/processor discovers evidence of, or reasonably suspects, a theft or diversion of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products during transport, the grower/processor shall immediately report its findings or suspicions 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, and to law enforcement.

(c) If a grower/processor discovers a discrepancy in the transport manifest, the grower/processor shall:

(1) Conduct an investigation.

(2) Amend the grower/processor's standard plan of operation, if necessary, to prevent future discrepancies between the quantity or description of inventory listed in the transport manifest and the quantity or description of inventory delivered.

(3) Submit a report of the investigation to the Department. The following requirements apply:

(i) The grower/processor shall submit a written preliminary report of the investigation to the Department within seven days of discovering the discrepancy.

- (ii) The grower/processor shall submit a final written report of the investigation to the Department within 30 days of discovering the discrepancy.

§ 1151a.39. Electronic tracking system.

A grower/processor shall use the electronic tracking system prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701).

§ 1151a.40. Management and disposal of medical marijuana waste.

- (a) Medical marijuana waste generated by a grower/processor or an approved laboratory shall be stored, collected and transported in accordance with 25 Pa. Code Chapter 285 (relating to storage, collection and transportation of municipal waste), provided the medical marijuana waste is not hazardous.
- (b) The following types of medical marijuana waste shall be rendered unusable and unrecognizable prior to being transported from a grower/processor or an approved laboratory:
  - (1) Unused, surplus, returned, recalled, contaminated or expired medical marijuana.
  - (2) Any medical marijuana plant material that is not used in the growing, harvesting or processing of medical marijuana, including flowers, stems, trim, leaves, seeds, dead medical marijuana plants, dead immature medical marijuana plants, unused medical marijuana plant parts, unused immature medical marijuana plant parts or roots.
- (c) Medical marijuana waste is unusable and unrecognizable if all components of the waste

are indistinguishable and incapable of being ingested, inhaled, injected, swallowed or otherwise used for certified medical use. Acceptable methods of rendering the waste unusable and unrecognizable include thermal treatment or melting; shredding, grinding or tearing; and incorporating the medical marijuana waste with other municipal waste.

- (d) Unusable and unrecognizable medical marijuana waste identified in subsection (b) and other solid or semi-solid medical marijuana waste that is not hazardous shall be disposed of at a permitted municipal waste landfill or processed at a permitted resource recovery facility or incinerator.
- (e) Wastewater or spent hydroponic nutrient solution generated or produced from the growing, harvesting or processing of immature medical marijuana plants or medical marijuana plants shall be managed in accordance with one of the following:
  - (1) Discharged into a permitted sewage treatment system in accordance with local, Federal and State requirements, including The Clean Streams Law (35 P.S. § § 691.1—691.1001) and 25 Pa. Code Chapter 92a (relating to National Pollutant Discharge Elimination System permitting, monitoring and compliance).
  - (2) Treated and discharged into waters of the Commonwealth under a National Pollutant Discharge Elimination System permit or water quality management permit in accordance with the requirements of The Clean Streams Law, including 25 Pa. Code Chapter 91 (relating to general provisions) and 25 Pa. Code Chapter 92a.
  - (3) Disposed in a municipal waste landfill if placed in a container that is less than one gallon in size.
- (f) Hazardous waste shall be managed in accordance with Federal and State law, rules and

regulations related to hazardous waste, including sections 3001—3024 of the Resource Conservation and Recovery Act of 1976 (42 U.S.C.A. § § 6921—6939g), the Solid Waste Management Act (35 P.S. § § 6018.101— 6018.1003) and regulations promulgated thereunder.

- (g) The type of medical marijuana waste identified in subsection (b)(2) may be composted and beneficially used at the grower/processor facility through a permit-by-rule provided the requirements of 25 Pa. Code § 271.103(d)(1)—(3) and (5) (relating to permit-by-rule for municipal waste processing facilities other than for regulated medical or chemotherapeutic waste; qualifying facilities; general requirements) are satisfied, and the compost is beneficially used at the grower/processor facility as a soil substitute, soil conditioner, soil amendment, fertilizer or mulch. The notice required under 25 Pa. Code § 271.103(d)(5) shall be submitted to the Solid Waste Manager of the Department of Environmental Protection’s regional office having jurisdiction over the grower/processor facility within 15 days of initiating the composting activity.

§ 1151a.42. Complaints about or recall of medical marijuana products.

- (a) A dispensary shall notify the Department and the grower/processor from which it obtained the medical marijuana product in question immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from using medical marijuana products purchased by the dispensary from the grower/processor. A grower/processor shall investigate the report. The following requirements apply:
  - (1) A grower/processor shall immediately investigate a complaint to determine if a

voluntary or mandatory recall of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products is necessary or if any further action is required.

- (2) If a grower/processor determines that further action is not required, the grower/processor shall notify the Department of its decision and, within 24 hours, submit a written report to the Department stating its rationale for not taking further action.
- (b) The following requirements apply to voluntary recalls:
- (1) A grower/processor may voluntarily recall seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products from the market at its discretion for reasons that do not pose a risk to public health and safety.
  - (2) If a grower/processor initiates a recall for a reason that does not pose a risk to public health and safety, the grower/processor shall notify the Department at the time the grower/processor begins the recall.
- (c) The following requirements apply to mandatory recalls:
- (1) 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, the grower/processor shall:
    - (i) Immediately notify the Department by phone.
    - (ii) Secure, isolate and prevent the distribution of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical

marijuana products that may have been affected by the condition and remains in its possession. The grower/processor may not dispose of affected seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products prior to notifying the Department and coordinating the disposal with the Department.

- (2) If a grower/processor fails to cooperate with the Department in a recall, or fails to immediately notify the Department of a need for a recall under paragraph (1), the Department may seek a cease and desist order under § 1141a.47 (relating to general penalties and sanctions) and the grower/processor may be subject to any other penalties or sanctions provided for in the act or this part.
- (d) A grower/processor's recall plan must include the following:
- (1) Designation of one or more employees to serve as the recall coordinators. A recall coordinator shall be responsible for, among other duties, accepting the recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.
  - (2) Procedures for identifying and isolating the affected seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to prevent or minimize its distribution to patients, caregivers and other medical marijuana organizations and approved laboratories.
  - (3) Procedures to retrieve and dispose of the affected seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.
  - (4) A communications plan to notify those affected by the recall, including:

- (i) The manner in which the grower/processor will notify other medical marijuana organizations or approved laboratories in possession of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products subject to the recall.
  - (ii) The use of press releases and other appropriate notifications to ensure that patients and caregivers are notified of the recall if affected medical marijuana products were dispensed to patients and caregivers.
- (5) Procedures for notifying the Department.
- (6) Procedures for entering information relating to the recall into the grower/processor's electronic tracking system.
- (e) A grower/processor shall follow the procedures outlined in its recall plan, unless the grower/processor obtains the prior written approval of the Department. The grower/processor shall conduct recall procedures in a manner that maximizes the recall of affected seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products and minimizes risks to public health and safety.
- (f) A grower/processor shall coordinate the disposal of recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products with the Department. The Department or its authorized agents may oversee the disposal to ensure that the recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products are disposed of in a manner that will not pose a risk to public health and safety.
- (g) The grower/processor shall enter information relevant to the recall into the electronic tracking system as part of the daily inventory, including:

- (1) The total amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, including types, forms, harvest batches, harvest lots and process lots, if applicable.
- (2) The amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products received by the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable, by date and time.
- (3) The total amount of recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products returned to the grower/processor, including types, forms, harvest batches, harvest lots and process lots, if applicable.
- (4) The names of the recall coordinators.
- (5) From whom the recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products were received.
- (6) The means of transport of the recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.
- (7) The reason for the recall.
- (8) The number of recalled samples or test samples, types, forms, harvest batches, harvest lots and process lots, if applicable, sent to approved laboratories, the names and addresses of the approved laboratories, the dates of testing and the results by sample or test sample.
- (9) The manner of disposal of the recalled seeds, immature medical marijuana plants,

medical marijuana plants, medical marijuana or medical marijuana products, including:

- (i) The name of the individual overseeing the disposal of the recalled seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.
  - (ii) The name of the disposal company, if applicable.
  - (iii) The method of disposal.
  - (iv) The date of disposal.
  - (v) The amount disposed of by types, forms, harvest batches, harvest lots and process lots, if applicable.
- (10) Any other information required by the Department.
- (h) 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.

§ 1151a.43. Pesticides.

- (a) The use of a pesticide by a grower/processor in the growing or processing of seeds, immature medical marijuana plants, medical marijuana plants or medical marijuana shall be in accordance with the Pennsylvania Pesticide Control Act of 1973 (Pesticide Control Act) (3 P.S. § § 111.21—112) and this part.
- (b) The Department and the Department of Agriculture will cooperate to inspect for and

enforce the requirements of this section.

(c) The following apply regarding recordkeeping requirements for pesticide applications:

(1) The grower/processor shall maintain a record of each application of a pesticide.

The record must include the following information:

(i) The date of application. For a pesticide requiring a re-entry time, the date of application must include the hour completed.

(ii) The place of application, including the specific block, section, or immature medical marijuana plants or medical marijuana plants treated.

(iii) The size of the area treated.

(iv) The product name of every pesticide used.

(v) The United States Environmental Protection Agency product registration number. This requirement is unnecessary for products exempted under section 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.A. § 136w).

(vi) The total amount of every pesticide used in pounds, ounces, gallons or liters applied to a treated area.

(vii) The dosage or rate of application of every pesticide used.

(viii) If applicable, the employee identification numbers of the individuals involved in making the pesticide and the permit or certification numbers of the individuals making or supervising the application.

(ix) Copies of pesticide labels and Safety Data Sheets for the pesticides used at the facility.

(2) A record required to be kept under this section shall be completed within 24 hours

of the completion of the application and maintained for at least four years. A record shall be made immediately available to the Department or its authorized agents and medical personnel or first responders in an emergency. A record shall be made available to the Department of Agriculture upon request.

- (d) For purposes of enforcement, the Pesticide Control Act, 3 P.S. § § 111.21—112, and 7 Pa. Code Chapter 128 (relating to pesticides) are incorporated by reference and adopted as standards for use by the Department of Agriculture, in coordination with the Department, in enforcing this section.
- (e) A grower/processor shall only use the pesticide active ingredients in Appendix A in the growing and processing of seeds, immature medical marijuana plants, medical marijuana plants or medical marijuana.
- (f) The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

*Defoliant*—A substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

*Desiccant*—A substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

*Pesticide*—A substance or mixture of substances intended for preventing, destroying, repelling or mitigating a pest, and a substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.

*Plant regulator*—

- (i) A substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise

altering the behavior of plants or the produce thereof, but may not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants and soil amendments.

- (ii) The term does not include any of the nutrient mixtures or soil amendments commonly known as vitamin-hormone horticultural products, which are intended for improvement, maintenance, survival, health and propagation of plants, and are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

§ 1151a.44. Treatment and quarantine orders.

- (a) If a grower/processor fails or refuses to eradicate a plant pest that is found at its facility, the Department, in cooperation with the Department of Agriculture, may issue and enforce a treatment order against the grower/processor, including an order to eradicate, for any immature medical marijuana plants or medical marijuana plants that may carry or harbor the plant pest. The order will be issued in writing and set forth the necessary treatment, control or eradication measures required. If the grower/processor fails or refuses to comply with the order, the Department, acting in cooperation with the Department of Agriculture, may carry out the control measures established in the treatment order with all expenses associated with the measures accruing to the grower/processor.
- (b) The Department of Agriculture, acting with the cooperation of the Department, may establish a quarantine to prevent the dissemination of plant pests within this Commonwealth or to prevent or delay the introduction of a plant pest into this Commonwealth from any country, state or territory. The following requirements apply:

- (1) Upon finding a plant pest in a facility that has the potential to cause serious damage to other grower/processors or to agriculture in general, the geographic area in which the plant pest was found and any adjacent areas as the Department of Agriculture deems necessary may be quarantined.
- (2) The quarantine order will establish conditions and restrictions determined by the Department of Agriculture to be necessary to prevent or reduce the movement of the plant pest from the quarantined area. Vehicles or any means of conveyance suspected of carrying the plant pest may also be subject to quarantine and a treatment order under subsection (a) may be issued as necessary to eradicate the plant pest.
- (3) The quarantine order may regulate the planting, growing or harvesting of any immature medical marijuana plants or medical marijuana plants that serve as a host or reservoir for the plant pest within the quarantined area and may include prohibiting the processing of a specific harvest batch or harvest lot of medical marijuana within a specific geographic area or during a specified time period. An immature medical marijuana plant or medical marijuana plant suspected of harboring the plant pest may be ordered to be treated or destroyed.

#### **CHAPTER 1161 (Reserved)**

**§§ 1161.21—1161.41 (Reserved).**

#### CHAPTER 1161a. DISPENSARIES

§ 1161a.22. Dispensaries generally.

- (a) The qualifications that a dispensary shall meet to receive a permit are continuing qualifications to maintain the permit.
- (b) In addition to any other requirements in the act or this part, a dispensary shall comply with the following:
  - (1) A dispensary may not engage in the business of possessing, dispensing, selling or offering to dispense or sell medical marijuana products to a patient or caregiver in this Commonwealth without first being issued a permit by the Department and without first being determined operational by the Department as required under § 1141a.42 (relating to failure to be operational).
  - (2) A dispensary may not employ an individual at a facility who is under 18 years of age.
  - (3) A dispensary may not permit a patient to self-administer medical marijuana products at the facility unless the patient is also an employee of the dispensary, and the dispensary permits self-administration of medical marijuana products at the facility by the employees.

§ 1161a.23. Dispensing medical marijuana products.

- (a) A dispensary may only dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee at the facility who is authorized to dispense medical marijuana products at the facility.
- (b) Prior to dispensing medical marijuana products to a patient or caregiver, the dispensary shall:
  - (1) Verify the validity of the patient or caregiver identification card using the

electronic tracking system.

- (2) Review the information on the patient's most recent certification by using the electronic tracking system to access the Department's database. The following requirements apply:
  - (i) If a practitioner sets forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the medical marijuana product dispensed to a patient or a caregiver by a dispensary must conform to those recommendations, requirements or limitations.
  - (ii) If a practitioner does not set forth recommendations, requirements or limitations as to the form or dosage of a medical marijuana product on the patient certification, the physician, pharmacist, physician assistant or certified registered nurse practitioner employed by the dispensary and working at the facility shall consult with the patient or the caregiver regarding the appropriate form and dosage of the medical marijuana product to be dispensed.
  - (iii) The dispensary shall update the patient certification in the electronic tracking system by entering any recommendation as to the form or dosage of medical marijuana product that is dispensed to the patient.
- (c) Prior to the completion of the transaction, the employee conducting the transaction at the dispensary shall prepare a receipt of the transaction, and file the receipt information with the Department utilizing the electronic tracking system. A dispensary shall provide a copy of the receipt to the patient or the caregiver, unless the patient or the caregiver

declines the receipt. The receipt must include all of the following information:

- (1) The name, address and any permit number assigned to the dispensary by the Department.
  - (2) The name and address of the patient and, if applicable, the patient's caregiver.
  - (3) The date the medical marijuana product was dispensed.
  - (4) Any requirement or limitation noted by the practitioner on the patient's certification as to the form of medical marijuana product that the patient should use.
  - (5) The form and the quantity of medical marijuana product dispensed.
- (d) Except as provided in sections 2001—2003 of the act (35 P.S. § § 10231.2001—10231.2003) (relating to academic clinical research centers and clinical registrants) and this part, a dispensary shall destroy any paper copy of the patient certification or delete any electronically recorded patient certification stored on the dispensary's network, server or computer system as the result of a transaction after the receipt relating to that transaction has been filed under subsection (c).

§ 1161a.24. Limitations on dispensing.

- (a) A dispensary may not dispense to a patient or caregiver:
- (1) A quantity of medical marijuana product that is greater than the amount indicated on the patient's certification.
  - (2) A form or dosage of medical marijuana product that is listed as a restriction or limitation on the patient certification.
  - (3) A form of medical marijuana products not permitted by the act or this part, unless

otherwise provided in regulations adopted by the Department under section 1202 of the act (35 P.S. § 10231.1202) (relating to regulations based on recommendations of advisory board).

- (b) A dispensary may not dispense an amount of medical marijuana product greater than a 30-day supply to a patient or caregiver until the patient has exhausted all but a seven-day supply provided pursuant to the patient certification currently on file with the Department.

§ 1161a.25. Licensed medical professionals at facility.

- (a) Except as provided in subsection (b), a dispensary shall ensure that a physician or a pharmacist is present at the facility at all times during the hours the facility is open to dispense or to offer to dispense medical marijuana products to patients and caregivers.
- (b) If a dispensary is authorized to operate more than one facility under its permit, a physician assistant or a certified registered nurse practitioner may be present onsite at each of the other locations instead of a physician or pharmacist. The physician, pharmacist, physician assistant or certified registered nurse practitioner may rotate coverage of the facilities, provided that a physician or pharmacist is always present at one of the facilities.
- (c) As required under the act, a physician, a pharmacist, a physician assistant or a certified registered nurse practitioner shall, prior to assuming any duties at a facility, successfully complete a 4-hour training course developed by the Department. The course must provide instruction in the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana, and other information deemed necessary by the

Department.

- (d) Successful completion of the course required under subsection (c) shall be approved as continuing education credits as determined by:
  - (1) The State Board of Medicine and the State Board of Osteopathic Medicine.
  - (2) The State Board of Pharmacy.
  - (3) The State Board of Nursing.
- (e) A practitioner or a physician, while at the facility, may not issue a patient certification to a patient.

§ 1161a.26. Dispensary facilities.

- (a) A dispensary may only dispense medical marijuana products to a patient or caregiver in an indoor, enclosed, secure facility as approved by the Department.
- (b) A dispensary may not be located:
  - (1) Within 1,000 feet of a public, private or parochial school, or a day-care center providing services to children under the age of 18, measured from the property line of the public, private or parochial school, or day-care center nearest to the dispensary to the nearest physical wall of the dispensary.
  - (2) At the same site used for growing and processing medical marijuana.
  - (3) In the same office space as a practitioner or other physician.
- (c) The Department may waive or amend the prohibition under subsection (b)(1) if it is shown by clear and convincing evidence that the waiver or amendment is necessary to provide patients with adequate access to medical marijuana. A waiver or amendment by the Department under this subsection may require additional security measures, changes

to the physical plant of a facility or other conditions necessary to protect individuals under 18 years of age and to prevent unauthorized access to medical marijuana.

- (d) No one under 18 years of age is permitted to enter a dispensary unless the individual is a patient or accompanied by a parent, guardian or caregiver. If a dispensary facility is located adjacent to a commercial operation, the facility shall provide additional means of security satisfactory to the Department to prevent individuals under 18 years of age from entering the facility from the commercial operation unless the individual is accompanied by an adult.
- (e) The following areas of a dispensary facility must be clearly marked with proper signage:
  - (1) Limited access areas. All areas of ingress and egress to a limited access area must be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than 1/2 inch in height, which must state:  
  
Do Not Enter—Limited Access Area—Access Limited to Authorized Personnel and Escorted Individuals.
  - (2) Areas that are open to patients and caregivers.
- (f) A dispensary shall ensure that a facility has an enclosed, secure area out of public sight for the loading and unloading of medical marijuana products into and from a transport vehicle.

§ 1161a.27. Items and services provided at a dispensary.

- (a) A dispensary shall dispense the form of medical marijuana products under § 1161a.23(b)(2) (relating to dispensing medical marijuana products).

- (b) A dispensary shall purchase medical marijuana products only from a grower/processor.
- (c) A dispensary may sell, offer for sale or provide at a facility, with the prior written approval of the Department, instruments, devices and services related to the use of medical marijuana products.
- (d) A dispensary may dispense a medical marijuana product with a THC concentration of 0.3% or less so long as the dispensary purchases it from a grower/processor and the grower/processor obtained Department approval under § 1151a.28(b) (relating to forms of medical marijuana).
- (e) A dispensary may not:
  - (1) Provide medical marijuana products at no cost or free, unless the patient is approved for financial assistance by the Department.
  - (2) Make the dispensing of medical marijuana products to a patient or caregiver conditional upon:
    - (i) The purchase of a medical device, instrument or service provided at a dispensary facility.
    - (ii) The purchase of a medical device, instrument or service provided at a location other than a dispensary facility.
  - (3) Deliver, or contract to a third party the delivery of, medical marijuana products to a patient or caregiver at the patient's or caregiver's home or any other location.
  - (4) Sell, offer for sale or provide at a facility, items and services unrelated to the use of medical marijuana products.

§ 1161a.28. Labels and safety inserts.

- (a) Medical marijuana products dispensed by a dispensary must only be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical marijuana, the percentage of THC and CBD contained in the medical marijuana product, and any other labeling required by the Department.
- (b) A dispensary shall dispense medical marijuana products to a patient or caregiver in a sealed and properly labeled package.
- (c) The dispensary shall inspect the label to ensure that the label:
  - (1) Is easily readable.
  - (2) Is conspicuously placed on the package.
  - (3) Includes the name, address and permit number of the grower/processor.
  - (4) Lists the form and quantity of medical marijuana.
  - (5) Contains the following warning stating:

This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the practitioner who issued the certification and, in the case of breastfeeding, the infant’s pediatrician.

This product might impair the ability to drive or operate heavy machinery. Keep out of reach of children.
  - (6) Lists the number of individual doses contained within the package and the species and percentage of THC and CBD and other cannabinoids enumerated in § 1151a.29 (relating to limits on medical marijuana processing), and the individual terpenes and corresponding percentages.
  - (7) Contains a warning that the medical marijuana product must be kept in the original container in which it was dispensed.

- (8) Contains a warning that unauthorized use is unlawful and will subject the purchaser or user to criminal penalties.
  - (9) Includes the name and address of the dispensary.
  - (10) Includes the identification number of the sales clerk dispensing the medical marijuana products to the patient or caregiver and the patient identification number.
  - (11) Lists a use by or expiration date.
  - (12) Lists the packaging date.
  - (13) Includes instructions for proper storage of the medical marijuana product in the package.
  - (14) Contains any other information required by the Department.
  - (15) Is firmly affixed to the container directly holding medical marijuana and is firmly affixed to outer packaging if used.
- (d) The dispensary shall inspect the label to ensure that the label does not bear:
- (1) Any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available food or beverage product.
  - (2) Any statement, artwork or design that could reasonably lead an individual to believe that the package contains anything other than medical marijuana.
  - (3) Any seal, flag, crest, coat of arms or other insignia that could reasonably mislead an individual to believe that the product has been endorsed, manufactured or approved for use by any state, county or municipality or any agency thereof.
  - (4) Any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

- (e) When a dispensary dispenses medical marijuana products to a patient or caregiver, the dispensary shall also provide the patient or caregiver with a safety insert developed and approved by the Department that includes the following information:
- (1) The method or methods for administering individual doses of medical marijuana products.
  - (2) Any potential dangers stemming from the use of medical marijuana products.
  - (3) How to recognize what may be problematic usage of medical marijuana products and how to obtain appropriate services or treatment for problematic usage.
  - (4) The side effects and contraindications associated with medical marijuana products, if any, which may cause harm to the patient.
  - (5) How to prevent or deter the misuse of medical marijuana products by an individual under 18 years of age or others.
  - (6) Any other information determined by the Department to be relevant to enhance patient safety.

§ 1161a.29. Plans of operation.

- (a) At the time the Department determines a dispensary to be operational, the dispensary shall provide the Department with a full and complete plan of operation for review that includes the following:
- (1) Employment policies and procedures.
  - (2) Security policies and protocols, including:
    - (i) Staff identification measures.
    - (ii) Monitoring of attendance of staff and individuals requiring access to the

facility.

- (iii) Alarm systems.
  - (iv) Video surveillance.
  - (v) Monitoring and tracking inventory.
  - (vi) Personnel security.
- (3) A process for receiving, packaging, labeling, handling, tracking, transporting, storing, disposing, returning and recalling medical marijuana products in accordance with all applicable laws, rules and regulations.
  - (4) Workplace safety.
  - (5) Maintenance, cleaning and sanitation of the site or facility, or both.
  - (6) Inventory maintenance and reporting procedures.
  - (7) The investigation of complaints and potential adverse events from other medical marijuana organizations, patients, caregivers or practitioners.
  - (8) The use of the electronic tracking system prescribed by the Department.
- (b) A dispensary shall make the full and complete plan of operation available to the Department upon request and during any inspection of the site and facility.
  - (c) A dispensary shall comply with its plan of operation.

§ 1161a.30. Access to dispensary facilities.

- (a) A dispensary shall post a sign in a conspicuous location at each entrance of the facility that reads:

THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE.

ONLY EMPLOYEES, PATIENTS AND CAREGIVERS MAY ENTER. NO ONE

UNDER THE AGE OF 18 IS PERMITTED TO ENTER UNLESS THE INDIVIDUAL IS A PATIENT AND IS ACCOMPANIED BY A PARENT, GUARDIAN OR CAREGIVER.

- (b) Except as provided in subsection (c), only authorized employees of a dispensary may enter a limited access area.
- (c) When an individual who is not approved to enter the facility requires access to a limited access area in the dispensary facility in order to provide goods or services to the facility, a dispensary shall require the individual to present government-issued identification, to sign a log for that specific facility, detailing the need for entry, and to wear a temporary identification badge that is visible to others at all times while in a limited access area.
- (d) When admitting an individual under subsection (c) to a limited access area, a dispensary shall:
  - (1) Require the individual to sign a log and detail the need for entry upon entering and sign the log when leaving the limited access area.
  - (2) Check the individual's government-issued identification to verify that the name on the identification provided matches the name in the log. A photocopy of the identification must be retained with the log.
  - (3) Issue a temporary identification badge with the individual's name and company, if applicable, and a badge number.
  - (4) Escort the individual while the individual remains in a limited access area.
  - (5) Ensure that the individual does not touch any medical marijuana products located in a limited access area.
- (e) The following requirements apply regarding the log required under subsections (c) and

(d):

- (1) The dispensary shall maintain the log for four years and make the log available to the Department, State or local law enforcement and other State or local government officials upon request if necessary to perform the government officials' functions and duties.
  - (2) The log must include the full name of each individual granted access to the facility's limited access area, the temporary identification badge number, the time of arrival, the time of departure and the purpose of the visit, including the areas visited and the name of each employee visited.
- (f) This section does not limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government officials, from entering any area of a dispensary if necessary to perform the government officials' functions and duties that pertain to the act or this part.
- (g) A principal, financial backer, operator or an employee of a dispensary may not receive any type of consideration or compensation for allowing an individual to enter a limited access area.

§ 1161a.31. Security and surveillance.

- (a) A dispensary shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss. The security and surveillance systems must include all of the following:
- (1) A professionally-monitored security alarm system that includes the following:
    - (i) Coverage of all facility entrances and exits; rooms with exterior windows,

exterior walls, roof hatches or skylights; storage rooms, including those that contain medical marijuana and safes; and the perimeter of the facility.

- (ii) A silent security alarm system signal, known as a duress alarm, generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system.
- (iii) An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response.
- (iv) A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress.
- (v) An electrical, electronic, mechanical or other device capable of being programmed to send a prerecorded voice message requesting dispatch, when activated, over a telephone line, radio or other communication system to a law enforcement, public safety or emergency services agency.
- (vi) A failure notification system that provides an audible, text or visual notification of any failure in the systems. The failure notification system must provide by telephone, e-mail or text message an alert to a designated security person within the facility within five minutes after the failure.
- (vii) Smoke and fire alarms.
- (viii) Auxiliary power sufficient to maintain security and surveillance systems for at least 48 hours following a power outage.
- (ix) The ability to ensure all access doors are not solely controlled by an electronic access panel to prevent locks from becoming released during a

power outage.

- (x) Motion detectors.
- (2) A professionally-monitored security and surveillance system that is operational 24 hours per day, seven days per week and records all activity in images capable of clearly revealing facial detail. The security and surveillance system must include all of the following:
- (i) Fixed camera placement that allows for a clear image of all individuals and activities in and around the following:
    - (A) Any area of a facility where medical marijuana products are loaded or unloaded into or from transport vehicles.
    - (B) Entrances to and exits from a facility. Entrances and exits must be recorded from both indoor and outdoor vantage points.
    - (C) Rooms with exterior windows, exterior walls, roof hatches or skylights and storage rooms, including those that may contain medical marijuana products and safes.
    - (D) Five feet from the exterior of the perimeter of a facility.
    - (E) All limited access areas.
  - (ii) Auxiliary power sufficient to maintain security and surveillance systems for at least 48 hours following a power outage.
  - (iii) The ability to operate under the normal lighting conditions of each area under surveillance.
  - (iv) The ability to immediately produce a clear, color, still photograph in a digital format that meets the requirements of this subsection.

- (3) The ability to clearly and accurately display the date and time. The date and time must be synchronized and set correctly and may not significantly obscure the picture.
  - (4) The ability to record and store all images captured by each surveillance camera for a minimum of two years in a format that may be easily accessed for investigative purposes. The recordings must be kept:
    - (i) At the facility:
      - (A) In a locked cabinet, closet or other secure place to protect it from tampering or theft.
      - (B) In a limited access area or other room to which access is limited to authorized individuals.
    - (ii) At a secure location other than the location of the facility if approved by the Department.
  - (5) A security alarm system separate from the facility's primary security system covering the limited access area or other room where the recordings under paragraph (4) are stored. The separate security alarm system must meet the same requirements as the facility's primary security alarm system.
- (b) The following apply regarding the inspection, servicing or alteration of, and the upgrade to, the dispensary facility's security and surveillance systems:
- (1) The systems shall be inspected and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor.
  - (2) The dispensary shall conduct maintenance inspections once every month to ensure that any repairs, alterations or upgrades to the security and surveillance systems

are made for the proper operation of the systems.

- (3) The dispensary shall retain at the facility, for at least four years, records of all inspections, servicing, alterations and upgrades performed on the systems and shall make the records available to the Department and its authorized agents within two business days following a request.
- (4) In the event of a mechanical malfunction of the security or surveillance system that the dispensary anticipates will exceed a four-hour period, the dispensary shall notify the Department immediately and, with Department approval, provide alternative security measures that may include closure of the facility.
- (5) The dispensary shall designate an employee or employees to continuously monitor the security and surveillance systems at the facility.
- (6) The following requirements apply regarding records retention:
  - (i) Within two business days following a request, a dispensary shall provide up to four screen captures of an unaltered copy of a video surveillance recording to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.
  - (ii) If a dispensary has been notified in writing by the Department or its authorized agents, law enforcement, or other Federal, State or local government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, the dispensary shall retain an unaltered copy of the recording for four years or until the investigation or proceeding is closed or the entity conducting the

investigation or proceeding notifies the dispensary that it is not necessary to retain the recording, whichever is longer.

- (c) A dispensary shall install commercial-grade, nonresidential steel doors and door locks on each room where medical marijuana products are stored and shall install commercial grade, nonresidential doors and door locks on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals.
- (d) At all times, all entrances to and exits from the facility must be securely locked.
- (e) A dispensary shall have an electronic back-up system for all electronic records.
- (f) A dispensary shall install lighting to ensure proper surveillance inside and outside of the facility.
- (g) A dispensary shall limit access to a room in a facility containing security and surveillance monitoring equipment to persons who are essential to maintaining security and surveillance operations; Federal, State and local law enforcement; security and surveillance system service employees; the Department or its authorized agents; and other persons with the prior written approval of the Department. The following requirements apply:
  - (1) A dispensary shall make available to the Department or the Department's authorized agents, upon request, a current list of authorized employees and service employees or contractors who have access to any security and surveillance areas.
  - (2) A dispensary facility shall keep security and surveillance rooms locked at all times and may not use these rooms for any other purpose or function.

§ 1161a.32. Inventory data.

- (a) A dispensary shall maintain the following inventory data in its electronic tracking system:
  - (1) Medical marijuana products received from a grower/processor.
  - (2) Medical marijuana products dispensed to a patient or caregiver.
  - (3) Damaged, defective, expired or contaminated medical marijuana products awaiting return to a grower/processor or awaiting disposal.
- (b) A dispensary shall establish inventory controls and procedures to conduct monthly inventory reviews and annual comprehensive inventories of medical marijuana products at its facility.
- (c) A written or electronic record shall be created and maintained of each inventory which includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.

§ 1161a.33. Storage requirements.

- (a) A dispensary shall have separate and locked limited access areas for storage of medical marijuana products that are expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been opened or breached until the medical marijuana products are returned to a grower/processor, destroyed or otherwise disposed of as required under § 1151a.40 (relating to management and disposal of medical marijuana waste).
- (b) A dispensary shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds and pests.

§ 1161a.34. Sanitation and safety in a facility.

- (a) A dispensary shall maintain a facility in a sanitary condition to limit the potential for contamination or adulteration of the medical marijuana products stored in or dispensed at the facility. The following requirements apply:
  - (1) Trash shall be properly removed.
  - (2) Floors, walls and ceilings shall be kept in good repair.
  - (3) Adequate protection against pests shall be provided through the use of integrated pest management practices and techniques that identify and manage pest problems, and the regular disposal of trash to prevent infestation.
  - (4) Toxic cleaning compounds, sanitizing agents, solvents and pesticide chemicals must be labeled and stored in a manner that prevents contamination of medical marijuana products and in a manner that otherwise complies with other applicable laws and regulations.
- (b) An employee working in direct contact with medical marijuana products is subject to the restrictions on food handlers in 28 Pa. Code § 27.153 (relating to restrictions on food handlers). An employee shall otherwise conform to sanitary practices while on duty, including the following:
  - (1) Maintaining adequate personal hygiene.
  - (2) Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated and at all times before dispensing medical marijuana products to a patient or caregiver.
- (c) A dispensary shall provide adequate and convenient hand-washing facilities furnished

with running water at a temperature suitable for sanitizing hands. The following requirements apply:

- (1) A dispensary shall locate hand-washing facilities where good sanitary practices require employees to wash and sanitize their hands.
- (2) A dispensary shall provide effective nontoxic sanitizing cleansers and sanitary towel service or suitable hand drying devices.
- (d) A dispensary shall provide adequate, readily accessible lavatories that are maintained in a sanitary condition and in good repair.
- (e) A dispensary shall comply with all other applicable State and local building code requirements.

§ 1161a.35. Transportation of medical marijuana products.

- (a) A dispensary may transport and deliver medical marijuana products to a medical marijuana organization in this Commonwealth in accordance with this section. The following apply:
  - (1) Unless otherwise approved by the Department, a dispensary may deliver medical marijuana products to a medical marijuana organization only between 7 a.m. and 9 p.m. for the purposes of transporting medical marijuana products among the permittee's dispensary locations and returning medical marijuana products to a grower/processor.
  - (2) A dispensary may contract with a third-party contractor for delivery so long as the contractor complies with this section.
  - (3) A dispensary may not transport medical marijuana products to any location

outside of this Commonwealth.

- (4) A dispensary shall use a global positioning system to ensure safe, efficient delivery of the medical marijuana products to a medical marijuana organization.
- (b) Vehicles permitted to transport medical marijuana products must:
- (1) Be equipped with a secure lockbox located within a locking cargo area.
  - (2) Have no markings that would either identify or indicate that the vehicle is being used to transport medical marijuana products.
  - (3) Be capable of being temperature-controlled for perishable medical marijuana products, as appropriate.
  - (4) Maintain current State inspection and vehicle registrations.
  - (5) Be insured in an amount that is commercially reasonable and appropriate.
- (c) A transport vehicle shall be staffed with a delivery team consisting of at least two individuals and comply with the following:
- (1) At least one delivery team member shall remain with the vehicle at all times that the vehicle contains medical marijuana products.
  - (2) Each delivery team member shall have access to a secure form of communication with the dispensary, such as a cellular telephone, at all times that the vehicle contains medical marijuana products.
  - (3) Each delivery team member shall carry an identification badge or card at all times and shall, upon demand, produce it to the Department or its authorized agents, law enforcement or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

- (4) Each delivery team member shall have a valid driver's license.
- (5) While on duty, a delivery team member may not wear any clothing or symbols that may indicate ownership or possession of medical marijuana products.
- (d) Medical marijuana products stored inside the transport vehicle may not be visible from the outside of the transport vehicle.
- (e) Except as provided in subsection (h), a delivery team shall proceed in a transport vehicle from the dispensary facility, where the medical marijuana products are loaded, directly to the medical marijuana organization facility, where the medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple facilities, as appropriate, to deliver medical marijuana products.
- (f) A dispensary 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, any vehicle accidents, diversions, losses or other reportable events that occur during transport of medical marijuana products.
- (g) A dispensary shall notify the Department daily of its delivery schedule, including routes and delivery times, either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department.
- (h) A transport vehicle is subject to inspection by the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties. A transport vehicle may be

stopped and inspected along its delivery route or at any medical marijuana organization.

§ 1161a.36. Transport manifest.

- (a) A dispensary shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:
- (1) The name, address and permit number of the dispensary, and the name of and contact information for a representative of the dispensary who has direct knowledge of the transport.
  - (2) The name, address and permit number of the medical marijuana organization receiving the delivery, and the name of and contact information for a representative of the medical marijuana organization.
  - (3) The quantity, by weight or unit, of each medical marijuana harvest batch, harvest lot or process lot contained in the transport, along with the identification number for each harvest batch, harvest lot or process lot.
  - (4) The date and approximate time of departure.
  - (5) The date and approximate time of arrival.
  - (6) The transport vehicle's make and model and license plate number.
  - (7) The identification number of each member of the delivery team accompanying the transport.
- (b) When a delivery team delivers medical marijuana products to multiple facilities, the transport manifest must correctly reflect the specific medical marijuana products in transit. Each recipient shall provide the dispensary with a printed receipt for the medical marijuana products received.

- (c) All medical marijuana products being transported shall be labeled in accordance with §§ 1151a.34 and 1161a.28 (relating to packaging and labeling of medical marijuana products; and labels and safety inserts) and shall be transported in a secure lockbox located within a locking cargo area.
- (d) A dispensary shall provide a copy of the transport manifest to the recipient receiving the medical marijuana products described in the transport manifest. To maintain confidentiality, a dispensary may prepare separate manifests for each recipient.
- (e) A dispensary shall, if requested, provide a copy of the printed transport manifest, and any printed receipts for medical marijuana products being transported, to the Department or its authorized agents, law enforcement, or other Federal, State or local government officials if necessary to perform the government officials' functions and duties.

§ 1161a.37. Evidence of adverse loss during transport.

- (a) If a dispensary receiving a delivery of medical marijuana products from a medical marijuana organization discovers a discrepancy in the transport manifest that remains unresolved upon delivery, the dispensary shall refuse acceptance of the delivery and immediately report the discrepancy 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, and to the appropriate law enforcement authorities.
- (b) If a dispensary discovers evidence of, or reasonably suspects, a theft or diversion of medical marijuana products during transport, the dispensary shall immediately report its findings or suspicions 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, and to law enforcement.

- (c) If a dispensary discovers a discrepancy in the transport manifest, the dispensary shall:
  - (1) Conduct an investigation.
  - (2) Amend the dispensary's standard plan of operation, if necessary, to prevent future discrepancies between the quantity or description of inventory listed in the transport manifest and the quantity or description of inventory delivered.
  - (3) Submit a report of the investigation to the Department. The following requirements apply:
    - (i) The dispensary shall submit a written preliminary report of the investigation to the Department within seven days of discovering the discrepancy.
    - (ii) The dispensary shall submit a final written report of the investigation to the Department within 30 days of discovering the discrepancy.

§ 1161a.38. Complaints about or recall of medical marijuana products.

- (a) A dispensary shall notify the Department and the grower/processor from which it received the medical marijuana product in question immediately upon becoming aware of any complaint made to the dispensary by a patient, caregiver or practitioner who reports an adverse event from using medical marijuana products dispensed by the dispensary.
- (b) Upon notification by the grower/processor under § 1151 a.42 (relating to complaints about or recall of medical marijuana products), the dispensary shall cease dispensing the affected medical marijuana products immediately.

- (c) A dispensary shall coordinate the return of the recalled medical marijuana products with the grower/processor.

§ 1161a.39. Electronic tracking system.

A dispensary shall use the electronic tracking system prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701).

§ 1161a.40. Application for additional dispensary locations.

- (a) An applicant for a dispensary permit shall include a primary dispensary facility location, and may include up to two additional dispensary facility locations, in its initial permit application. A permittee may file an application under this section for additional dispensary facility locations at a later date.
- (b) A dispensary shall submit an application for additional dispensary locations on a form prescribed by the Department.
- (c) A dispensary submitting an application for additional dispensary locations shall include with the application the following fees:
  - (1) An application fee of \$5,000, which is nonrefundable.
  - (2) A permit fee of \$30,000 for each dispensary location being proposed. The permit fee shall be submitted with the application for additional dispensary locations and will be refunded if the permit is not granted.
- (d) A dispensary may not begin operations at an additional location until the Department approves the application for additional dispensary locations, in writing, under this section.

- (e) A dispensary submitting an application for additional dispensary locations shall follow the requirements in § 1141a.29 (relating to initial permit application) and this part.

## **CHAPTER 1171 (Reserved)**

### **§§ 1171.21—1171.39 (Reserved).**

#### **CHAPTER 1171a. LABORATORIES**

##### § 1171a.22. Laboratories generally.

- (a) A laboratory may not identify, collect, handle or conduct tests on samples from a grower/processor or conduct tests on test samples for the Department unless the laboratory has been approved by the Department under § 1171a.23 (relating to approval of laboratories) and has entered into a written contract with the grower/processor under § 1171a.29 (relating to testing requirements).
- (b) The Department will post on its web site a current list of approved laboratories.
- (c) An approved laboratory shall employ at least one director to oversee and be responsible for the identification, collection, handling and testing operations of the approved laboratory. A director shall have earned, from a college or university accredited by a National or regional accrediting authority, at least one of the following:
  - (1) A doctorate of science or an equivalent degree in chemistry, biology, or a subdiscipline of chemistry or biology.
  - (2) A master's level degree in a chemical or biological science and a minimum of two years post-degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.
  - (3) A bachelor's degree in a biological science and a minimum of four years post-

degree laboratory experience related to testing of medicinal or pharmaceutical products or other experience as approved by the Department.

- (d) A principal or employee of a medical marijuana organization may not also own, be employed by or be affiliated with an approved laboratory that has a contract with that medical marijuana organization.
- (e) An approval issued by the Department to a laboratory under this part is valid for two years from the date of issuance and is valid only for the laboratory named and the location specified in the approval.
- (f) An approval issued by the Department to a laboratory under this part is not transferable to any other person or any other location unless the laboratory obtains the prior written consent of the Department.

§ 1171a.23. Approval of laboratories.

- (a) A laboratory wishing to identify, collect, handle and conduct tests on samples and test samples and other items used by a grower/processor in the growing and processing of medical marijuana and medical marijuana products as required under the act and this part shall submit an application for approval to the Department on a form and in a manner prescribed by the Department.
- (b) An application submitted under this section must include the following information:
  - (1) The name and address of the laboratory applicant or its authorized agent.
  - (2) The name and address of the owner of the laboratory applicant, and, if applicable, the medical or pharmacy licensure information regarding the owner.
  - (3) The name of the laboratory applicant's proposed director and technical personnel

who are or will be employed by the laboratory at the location to be approved.

- (4) A copy of the laboratory applicant's most recent certificate of accreditation.
  - (5) Copies of the standard operating procedures and sampling procedures adopted by the laboratory applicant and approved by the accreditation body that issued the certificate of accreditation to the laboratory applicant.
  - (6) A list of the specialized laboratory equipment utilized or to be utilized by the laboratory applicant in its testing operations, including the manufacturer's name and the serial and model number of the equipment, and other specifications as may be required by the Department.
  - (7) A description of the tests which are capable of being conducted by the laboratory applicant at the location to be approved.
  - (8) A description of the laboratory applicant's quality assurance program, which must be in compliance with § 1171a.32 (relating to quality assurance program).
  - (9) The procedures to be followed to establish chain of custody when collecting samples or test samples.
  - (10) A copy of the evaluation process that the laboratory applicant uses or will use to monitor, evaluate and document the competency of employees when testing samples and test samples and overseeing quality assurance controls.
  - (11) Other information required by the Department.
- (c) By submitting an application for approval to the Department, a laboratory applicant consents to an investigation of any person, information or physical location the Department or its authorized agents deem appropriate for the Department to make a determination of the laboratory applicant's ability to meet the requirements under the act

and this part.

- (d) An application for approval submitted under this chapter must include a statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).
- (e) The Department may issue an approval under this chapter if the Department determines that the laboratory applicant is financially and professionally suitable to conduct the testing required under the act and this part.

§ 1171a.24. Suspension or revocation of an approval issued to a laboratory.

- (a) An approval issued by the Department under this chapter may be suspended or revoked if the Department determines that the approved laboratory has engaged in unethical practices or has failed to do any of the following:
  - (1) Maintain proper standards of accuracy.
  - (2) Comply with the requirements of the act or this part applicable to the approved laboratory.
- (b) An approval issued by the Department under this chapter may be revoked if the Department determines that the approved laboratory has engaged in any of the following conduct:
  - (1) Dishonest reporting.
  - (2) Repeated errors in conducting the required testing.
  - (3) Allowing unauthorized individuals to perform testing or to sign reports.
  - (4) Inclusion of false statements in the application for approval or renewal.
  - (5) Advertising of medical marijuana testing services to the general public.

- (6) Knowingly accepting a sample from an individual other than a grower/processor or a test sample from an individual other than the Department or an authorized agent of the Department.
- (7) Failure to maintain standard operating procedures approved by the accreditation body that issued the certificate of accreditation to the approved laboratory.
- (8) Failure to properly enter test results into the electronic tracking system.
- (9) Loss by the approved laboratory of its certificate of accreditation.

§ 1171a.25. Renewal of an approval issued to a laboratory.

An approved laboratory wishing to renew its approval under this chapter shall, not more than six months nor less than four months prior to the expiration of the approval, submit an application under § 1171a.23 (relating to approval of laboratories) and update the information required to be submitted with the application as necessary.

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

- (a) A grower/processor shall request that a sample be identified and collected by an approved laboratory from each harvest batch sufficient to perform stability testing at six-month intervals for a one-year period.
- (b) The stability test shall be performed to ensure product potency and purity and provide support for expiration dating.
- (c) An approved laboratory shall retain a sample from each harvest batch sufficient to provide for stability testing and properly store the sample for one year.

§ 1171a.27. Sampling procedures for testing.

- (a) An approved laboratory shall ensure that its employees prepare all samples in accordance with policies and procedures that include appropriate information necessary for identifying, collecting and transporting samples in a manner that does not endanger the integrity of the samples for any testing required by this part.
- (b) The sampling policies must, at a minimum, meet the following requirements:
  - (1) Be appropriate to the matrix being sampled.
  - (2) Be in accordance with guidance provided by the Department.
- (c) The sampling procedures must include the following procedures:
  - (1) Surveying the conditions in which the sample is being stored.
  - (2) Using appropriate sampling equipment and consistent procedures.
  - (3) Selecting and removing equal portions for each sample.
  - (4) Random or systematic taking of samples throughout the harvest batch or harvest lot.
  - (5) Obtaining a minimum number of samples based on harvest batch or harvest lot size.
  - (6) Checking all parts of the harvest batch when harvest lots are created from that harvest batch.
  - (7) Recording on a form prescribed by the Department all observations and procedures used when collecting the sample.
  - (8) Creating a unique sample identification number that will be linked to the harvest batch or harvest lot number assigned by the grower/processor in the electronic tracking system.

- (9) Entering all required information into the electronic tracking system.

§ 1171a.28. Selection protocols for samples.

- (a) An employee of an approved laboratory may only enter a grower/processor facility for the purpose of identifying and collecting samples and shall have access to limited access areas in the facility for these purposes.
- (b) An employee identifying and collecting samples under subsection (a) shall follow the chain of custody procedures included in the approved laboratory's application and approved by the Department.
- (c) While at a grower/processor facility, an employee of an approved laboratory shall identify and collect the following for testing:
  - (1) Samples at the time of harvest.
  - (2) Samples of medical marijuana product before being sold or provided to a dispensary.
  - (3) Test samples at other times when requested by the Department.

§ 1171a.29. Testing requirements.

- (a) Prior to conducting any testing of a sample at the request of a grower/processor, an approved laboratory shall enter into a written contract with the grower/processor for testing services. The approved laboratory shall provide a copy of the contract to the Department within two days following the Department's request.
- (b) A grower/processor shall submit through the electronic tracking system a request to the approved laboratory with which it has a written contract under subsection (a) for each test

to be conducted.

- (c) At a minimum, testing, as prescribed by the Department, shall be performed as follows:
  - (1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.
  - (2) An approved laboratory other than the one that tested the harvest batch or harvest lot shall test samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.
- (d) The samples identified in subsection (c) shall be tested, at a minimum, for the following:
  - (1) Pesticides.
  - (2) Solvents.
  - (3) Water activity and moisture content.
  - (4) THC and CBD concentration.
  - (5) Microbiological contaminants.
  - (6) Terpenes.
- (e) 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 to ensure that all harvest batches, harvest lots and medical marijuana products are adequately tested for contaminants and that the cannabinoid profile is consistent throughout the harvest batch, harvest lot or medical marijuana products.
- (f) An approved laboratory may not test any samples when there is evidence of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection of the sample and testing, or any other factor sufficient to render the findings of questionable validity.

- (g) An approved laboratory shall enter test results for samples collected pursuant to § 1171a.28(c) (relating to selection protocols for samples) into the electronic tracking system and, under § 1151a.40 (relating to management and disposal of medical marijuana waste), properly dispose of all tested and untested samples and test samples.

§ 1171a.30. Standards for testing.

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.

§ 1171a.31. Test results and reporting.

- (a) Only the results of the following tests are in compliance with the testing requirements of this chapter:
  - (1) Tests conducted on harvest batch samples or harvest lot samples requested by a grower/processor under § 1171a.29 (relating to testing requirements) and identified and collected by an employee of an approved laboratory.
  - (2) Tests conducted on process lot samples requested by a grower/processor under § 1171a.29 and identified and collected by either an employee of a grower/processor or an employee of an approved laboratory.
- (b) The test results for each sample collected pursuant to § 1171a.28(c) (relating to selection protocols for samples) shall be entered into the electronic tracking system and shall only be accessible to the grower/processor submitting the sample and to the Department.
- (c) If a sample fails any test required under § 1171a.29, the following apply to the sample:

- (1) The approved laboratory that performed the initial test may re-test the sample upon a request from the grower/processor in accordance with subsection (d).
  - (2) If the sample passes the re-test, another approved laboratory shall sample the same harvest batch, harvest lot or process lot to confirm the passing test result.
  - (3) If the Department does not agree to accept the confirming results from the approved laboratory, the sample shall be disposed of by the approved laboratory under § 1151a.40 (relating to management and disposal of medical marijuana waste).
  - (4) If the re-tested sample fails, the lot shall be disposed of under § 1151a.40.
- (d) A grower/processor shall notify the Department and the approved laboratory through the electronic tracking system of its intent to re-test the sample or test another sample from the same harvest batch, harvest lot or process lot that failed a test.
- (e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include the following information:
- (1) Whether the chemical profile of the harvest batch, harvest lot or process lot conforms to the chemical profile of the strain as determined by the Department for the following compounds:
    - (i) THC.
    - (ii) THCA.
    - (iii) CBD.
    - (iv) CBDA.

- (v) CBC.
  - (vi) CBN.
  - (vii) THCV.
  - (viii) CBDV.
  - (ix) CBG.
  - (x) D8
- (2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the levels as determined by the Department for the following:
- (i) Heavy metals, mercury, lead, cadmium or arsenic.
  - (ii) Foreign material such as hair, insects, or any similar or related adulterant.
  - (iii) Any microbiological impurity, including:
    - (A) Total aerobic microbial count.
    - (B) Total yeast mold count.
    - (C) *P. aeruginosa*.
    - (D) *Aspergillus* spp.
    - (E) *S. aureus*.
    - (F) Aflatoxin B1, B2, G1 and G2.
    - (G) Ochratoxin A.
    - (H) Pesticide residue.
  - (iv) Whether the harvest batch, harvest lot or process lot is within the specification for the strain for the characteristics of:
    - (A) Odor.

- (B) Appearance.
- (C) Fineness.
- (D) Moisture content.

§ 1171a.32. Quality assurance program.

- (a) An approved laboratory shall establish and implement a quality assurance program to ensure that measurements are accurate, errors are controlled, and devices used for testing are routinely and properly calibrated.
- (b) The quality assurance program required under subsection (a) must include the following components:
  - (1) An organizational chart that includes the testing responsibilities of each employee of the approved laboratory named in the chart.
  - (2) A description of sampling procedures to be utilized.
  - (3) Appropriate chain of custody protocols.
  - (4) Analytical procedures.
  - (5) Data reduction and validation procedures.
  - (6) A plan for implementing corrective action, when necessary.
  - (7) A requirement for the provision of quality assurance reports to management.
  - (8) A description of the internal and external quality control systems.

§ 1171a.33. Transporting samples.

- (a) An employee of an approved laboratory, grower/processor or third-party contractor shall follow the transportation requirements under §§ 1151a.35 and 1151a.36 (relating to

transportation of medical marijuana; and transport manifest) when transporting a sample or test sample under this part.

- (b) An employee of an approved laboratory, grower/processor or third-party contractor who transports process lot samples from a grower/processor to an approved laboratory shall:
  - (1) Protect the physical integrity of the sample.
  - (2) Keep the composition of the sample intact.
  - (3) Protect the sample against factors that interfere with the validity of testing results, including the factors of time, temperature and other environmental factors that may work to jeopardize the integrity of the sample.

§ 1171a.34. Department request for testing.

- (a) The Department, in its sole discretion, may identify and collect a test sample from a grower/processor at any time and request an approved laboratory to conduct proficiency testing, conduct quality assurance measures and perform tests under this chapter.
- (b) The approved laboratory shall provide the Department with a written report of the test results from a test sample tested under subsection (a) within seven days of the collection of the test sample, or sooner if requested by the Department.

§ 1171a.35. Laboratory reporting.

- (a) An approved laboratory shall enter into the electronic tracking system the following information for each sample collected pursuant to § 1171a.28(c) (relating to selection protocols for samples) and each test conducted:
  - (1) The unique sample identification number the approved laboratory assigns to the

sample.

- (2) The name of the grower/processor that supplied the sample.
  - (3) The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.
  - (4) The date and time the sample was collected from the grower/processor.
  - (5) The date and time the sample was received by the approved laboratory.
  - (6) The date the test was completed.
  - (7) The condition of the sample when it was received by the approved laboratory.
  - (8) A description of each test performed.
  - (9) The results from the certificate of analysis issued under § 1171a.31 (relating to test results and reporting).
  - (10) The date the testing results were provided to the grower/processor under § 1171a.31 or the Department under § 1171a.34 (relating to Department request for testing).
- (b) An approved laboratory shall keep for four years a paper or electronic copy of the certificate of analysis performed on samples submitted by a grower/processor or test samples submitted by the Department including test results not required to be entered into the electronic tracking system under § 1171a.29 (relating to testing requirements).
- (1) Regarding tests results not entered into the electronic tracking system, the approved laboratory shall immediately provide to the Department an electronic copy of the certificate of analysis.
  - (2) Regarding test results entered into the electronic tracking system, the approved laboratory shall provide a copy of a certificate of analysis to the Department

within two days of a request made by the Department.

- (c) The Department may conduct an investigation based on the results shown on any certificate of analysis.

§ 1171a.36. Advertising.

- (a) An approved laboratory may not advertise, market or otherwise promote its medical marijuana testing services to the general public.
- (b) An approved laboratory may only promote its medical marijuana testing services to a grower/processor. An approved laboratory may use advertising, marketing and promotional materials directed at a grower/processor to promote its medical marijuana testing services. The advertising, marketing and promotional materials proposed to be used by an approved laboratory under this section shall be reviewed and approved by the Department prior to circulation or other use.
- (c) Personal solicitation by an employee, representative or agent of an approved laboratory to a grower/processor is considered advertising, marketing or otherwise promoting its medical marijuana testing services for the purposes of this section.
- (d) An approved laboratory may only advertise, market or otherwise promote its medical marijuana testing services that are performed onsite at the location designated in the laboratory's application.
- (e) A sign installed at the location of an approved laboratory that is designed to identify the laboratory or access to the laboratory is permissible as long as the sign meets local zoning requirements and does not violate the provisions of this section.

§ 1171a.37. Ownership prohibition.

The following individuals may not have a management, a direct or indirect financial, or other ownership interest in an approved laboratory:

- (1) A principal, owner, financial backer or employee of a medical marijuana organization.
- (2) A practitioner.
- (3) A physician, pharmacist, physician assistant or certified registered nurse practitioner who is currently employed by a medical marijuana organization.
- (4) Any other person, other than a patient, who may receive a direct or indirect financial benefit from the growing, processing, transporting, dispensing or selling of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

§ 1171a.38. Appeals.

Chapter 5, Subchapter A of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

**CHAPTER 1181 (Reserved)**

**§§ 1181.21—1181.34 (Reserved).**

CHAPTER 1181a. PHYSICIANS AND PRACTITIONERS

§ 1181a.22. Practitioners generally.

- (a) The qualifications that a physician shall meet to be registered with the Department and approved as a practitioner are continuing qualifications.
- (b) A physician may not issue a patient certification without being registered by the Department as a practitioner in accordance with § 1181a.24 (relating to physician registration).
- (c) A practitioner shall notify a dispensary by telephone of a patient's adverse reaction to medical marijuana products dispensed by that dispensary immediately upon becoming aware of the reaction.
- (d) A practitioner may petition the Medical Marijuana Advisory Board (Board) for the Board to review on a continuing basis, and recommend to the Secretary for approval, that serious medical conditions be changed, reduced or added to those conditions for which medical marijuana is likely to provide therapeutic or palliative benefit to a patient.

§ 1181a.23. Medical professionals generally.

- (a) The qualifications that a medical professional shall meet to be employed by a dispensary are continuing qualifications.
- (b) A medical professional may not assume any duties at a dispensary until the training required under § 1181a.32 (relating to training) and any other requirements for medical professionals under the act and this part are completed.
- (c) A medical professional shall notify by telephone the practitioner listed on a patient certification of a patient's adverse reaction to medical marijuana products dispensed by that dispensary immediately upon becoming aware of the reaction.

§ 1181a.24. Physician registration.

- (a) A physician who has an active and unrestricted medical license in this Commonwealth in accordance with the Medical Practice Act of 1985 (63 P.S. § § 422.1—422.51a) or the Osteopathic Medical Practice Act (63 P.S. § § 271.1—271.18) may file an application for registration with the Department as a practitioner on a form prescribed by the Department.
- (b) An application for registration must include, at a minimum, the following requirements:
  - (1) The physician's full name, business address, professional e-mail address, telephone numbers and, if the physician owns or is affiliated with a medical practice, the name of the medical practice.
  - (2) The physician's credentials, education, specialty, training and experience, and supporting documentation when available.
  - (3) The physician's medical license number.
  - (4) A certification by the physician that states:
    - (i) That the physician's Pennsylvania license to practice medicine is active and in good standing.
    - (ii) Whether the physician has been subject to any type of professional disciplinary action that would prevent the physician from carrying out the responsibilities under the act and this part, together with, if applicable, an explanation of the professional disciplinary action.
    - (iii) That the physician does not hold a direct or economic interest in a medical marijuana organization.

- (5) A statement that a false statement made by a physician in an application for registration is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).
- (c) Based on the information provided by the physician under subsection (b), the Department will determine whether to approve the physician to issue patient certifications.
- (d) The Department may list a physician on the practitioner registry only after the physician has successfully completed the training course required under § 1181a.32 (relating to training) and any other requirements for registration under the act and this part.

§ 1181a.25. Practitioner registry.

- (a) The Department will maintain a practitioner registry for use by a patient or caregiver registered by the Department. The practitioner registry will include only the practitioner's name, business address and medical credentials.
- (b) The inclusion of a physician in the practitioner registry will be subject to annual review by the Department to determine if the physician's license is inactive, expired, suspended, revoked, limited or otherwise restricted by the applicable Medical Board, or if the physician has been subject to professional disciplinary action.

§ 1181a.26. Denial, revocation or suspension of a practitioner registration.

- (a) A practitioner registration will be denied, revoked or suspended if the practitioner's medical license is inactive, expired, suspended, revoked, limited or otherwise restricted by the applicable Medical Board.
- (b) A practitioner registration may be denied, revoked or suspended if the practitioner is or

has been the subject of professional disciplinary action, including an immediate temporary action.

- (c) A physician who has been denied registration or whose practitioner registration has been revoked or suspended may reapply to the Department for inclusion in the practitioner registry in accordance with § 1181a.24 (relating to physician registration) if the event that led to the physician's denial, revocation or suspension has been resolved and the physician's medical license is designated as active without limitation by the applicable Medical Board. The physician's application for registration under this subsection must include evidence of the resolution.
- (d) A physician who has been denied registration or whose practitioner registration has been revoked or suspended may not do any of the following:
  - (1) Have electronic access to a patient certification.
  - (2) Issue or modify a patient certification.
  - (3) Provide a copy of an existing patient certification to any person, including a patient or a caregiver, except in accordance with applicable law.
- (e) The Department may revoke or suspend the registration of a practitioner for any of the following:
  - (1) A violation of the act or this part.
  - (2) A violation of an order issued under the act or this part.
  - (3) A violation of a regulation promulgated under the act.
  - (4) For conduct or activity that would have disqualified the practitioner from receiving a registration.
  - (5) Pending the outcome of a hearing in a case which the practitioner's registration

could be suspended or revoked.

§ 1181a.27. Issuing patient certifications.

- (a) A practitioner may issue a patient certification to a patient if the following conditions are met:
  - (1) The practitioner has determined, based upon a patient consultation and any other factor deemed relevant by the practitioner, that the patient has a serious medical condition and has included that condition in the patient's health care record.
  - (2) The practitioner has determined the patient is likely to receive therapeutic or palliative medical benefit from the use of medical marijuana based upon the practitioner's professional opinion and review of the following:
    - (i) The patient's prior medical history as documented in the patient's health care records if the records are available for review.
    - (ii) The patient's controlled substance history if the records are available in the Prescription Drug Monitoring Program.
- (b) Notwithstanding subsection (a), the following requirements apply:
  - (1) A practitioner who is not board-eligible or board-certified in pediatrics or a pediatric specialty, neurology with special qualifications in child neurology, child and adolescent psychiatry, or adolescent medicine (whether through pediatrics, internal medicine or family practice) may not issue a patient certification to a minor patient.
  - (2) Paragraph (1) will be effective upon the registration of a sufficient number of eligible practitioners to ensure adequate access for minor patients needing

services under the act and this part based on location, serious medical condition and number of patients, specialty, and number and availability of practitioners.

The Department will publish a notice in the *Pennsylvania Bulletin* 1 month before paragraph (1) becomes effective, stating that a sufficient number of eligible practitioners have registered to effectuate this subsection.

(c) A patient certification that is issued by a practitioner must include, at a minimum, all of the following:

- (1) The patient's name, home address, telephone number, date of birth and e-mail address, if available.
- (2) The practitioner's name, business address, telephone numbers, professional e-mail address, medical license number, area of specialty, if any, and signature.
- (3) The date of the patient consultation for which the patient certification is being issued.
- (4) The patient's specific serious medical condition.
- (5) A statement by the practitioner that the patient has a serious medical condition, and the patient is under the practitioner's continuing care for the condition.
- (6) A statement as to the length of time, not to exceed one year, for which the practitioner believes the use of medical marijuana by the patient would be therapeutic or palliative.
- (7) A statement by the practitioner that includes one of the following:
  - (i) The recommendations, requirements or limitations as to the form or dosage of medical marijuana product.
  - (ii) The recommendation that only a medical professional employed by the

dispensary and working at the dispensary facility consult with the patient or the caregiver regarding the appropriate form and dosage of the medical marijuana product to be dispensed.

- (8) A statement by the practitioner that the patient is terminally ill, if applicable.
  - (9) Any other information that the practitioner believes may be relevant to the patient's use of medical marijuana products.
  - (10) A statement that the patient is homebound or an inpatient during the time for which the patient certification is issued due to the patient's medical and physical condition and is unable to visit a dispensary to obtain medical marijuana products.
  - (11) A statement that the practitioner has explained the potential risks and benefits of the use of medical marijuana products to the patient and has documented in the patient's health care record that the explanation has been provided to the patient and informed consent has been obtained.
  - (12) A statement that a false statement made by the practitioner in the patient certification is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).
- (d) Upon completion of a patient certification, a practitioner shall:
- (1) Provide a copy of the patient certification to the patient or the patient's caregiver, if the patient is a minor, and to an adult patient's caregiver if authorized by the patient.
  - (2) Provide the patient certification with the original signature to the Department, which may be submitted electronically.
  - (3) File a copy of the patient certification in the patient's health care record.

§ 1181a.28. Modifying a patient certification.

- (a) 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 of the intent to modify the patient certification.
- (b) After modifying a patient certification, a practitioner shall do the following:
  - (1) Provide a copy of the patient certification to the patient or the patient's caregiver, if the patient is a minor, and to an adult patient's caregiver if authorized by the patient.
  - (2) Provide the patient certification with the original signature to the Department, which may be submitted electronically.
  - (3) File a copy of the patient certification in the patient's health care record.

§ 1181a.29. Revocation of a patient certification.

- (a) A practitioner shall immediately notify the Department in writing if the practitioner knows or has reason to know that any of the following events are true with respect to a patient for whom the practitioner issued a patient certification:
  - (1) The patient no longer has the serious medical condition for which the patient certification was issued.
  - (2) The use of medical marijuana products by the patient would no longer be therapeutic or palliative.
  - (3) The patient has died.

- (b) The Department will revoke a patient certification upon receiving notification of the occurrence of an event listed in subsection (a).
- (c) Notwithstanding subsection (a), a practitioner may withdraw the issuance of a patient certification at any time by notifying, in writing, both the patient and the Department.
- (d) The Department will immediately notify a medical marijuana cardholder upon the revocation of a patient certification and the information shall be entered into the electronic tracking system.

§ 1181a.30. Prescription Drug Monitoring Program.

- (a) A practitioner shall review the Prescription Drug Monitoring Program prior to issuing or modifying a patient certification to determine the controlled substance history of the patient to determine whether the controlled substance history of the patient would impact the patient's use of medical marijuana products.
- (b) A practitioner may access the Prescription Drug Monitoring Program to do any of the following:
  - (1) Determine whether a patient may be under treatment with a controlled substance by another physician or other person.
  - (2) Allow the practitioner to review the patient's controlled substance history as deemed necessary by the practitioner.
  - (3) Provide to the patient, or caregiver if authorized by the patient, a copy of the patient's controlled substance history.

§ 1181a.31. Practitioner prohibitions.

- (a) A practitioner may not accept, solicit or offer any form of remuneration from or to any individual, prospective patient, patient, prospective caregiver, caregiver or medical marijuana organization, including an employee, financial backer or principal, to certify a patient, other than accepting a fee for service with respect to a patient consultation of the prospective patient to determine if the prospective patient should be issued a patient certification to use medical marijuana products.
- (b) A practitioner may not hold a direct or economic interest in a medical marijuana organization.
- (c) A practitioner may not advertise the practitioner's services as a practitioner who can certify a patient to receive medical marijuana products.
- (d) A practitioner may not issue a patient certification for the practitioner's own use or for the use of a family or household member.
- (e) A practitioner may not be a designated caregiver for a patient that has been issued a patient certification by that practitioner.
- (f) A practitioner may not receive or provide medical marijuana product samples.
- (g) A practitioner may not excessively charge a patient for any expense related to the certification and follow-up process.

§ 1181a.32. Training.

- (a) Within the time specified, the following individuals shall complete a four-hour training course approved by the Department:
  - (1) A physician prior to being included in the practitioner registry under § 1181a.24

(relating to physician registration).

- (2) A medical professional prior to assuming any duties at a dispensary under § 1161a.25 (relating to licensed medical professionals at facility).
- (b) The requirements of the training course required under subsection (a) must include, at a minimum, all of the following:
- (1) The provisions of the act and this part relevant to the responsibilities of a practitioner or medical professional.
  - (2) General information about medical marijuana under Federal and State law.
  - (3) The latest scientific research on the endocannabinoid system and medical marijuana, including the risks and benefits of medical marijuana.
  - (4) Recommendations for medical marijuana as it relates to the continuing care of a patient in the following areas:
    - (i) Pain management, including opioid use in conjunction with medical marijuana.
    - (ii) Risk management, including drug interactions, side effects and potential addiction from medical marijuana use.
    - (iii) Palliative care.
    - (iv) The misuse of opioids and medical marijuana.
    - (v) Recommendations for use of medical marijuana and obtaining informed consent from a patient.
    - (vi) Any other area determined by the Department.
  - (5) Use of the Prescription Drug Monitoring Program.
  - (6) Best practices for recommending the form and dosage of medical marijuana

products based on the patient’s serious medical condition and the practitioner’s or medical professional’s medical specialty and training.

- (c) Successful completion of the course required under subsection (a) shall be approved as continuing education credits as determined by:
  - (1) The State Board of Medicine and the State Board of Osteopathic Medicine.
  - (2) The State Board of Pharmacy.
  - (3) The State Board of Nursing.
- (d) The individuals listed in subsection (a) shall submit documentation of the completion of the four-hour training course to the Department.
- (e) The Department will maintain on its publicly-accessible web site a list of approved training providers that offer the four-hour training course.

§ 1181a.33. Appeals.

Chapter 5, Subchapter A of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

**CHAPTER 1191 (Reserved)**

**§§ 1191.21—1191.34 (Reserved)**

CHAPTER 1191a. PATIENTS AND CAREGIVERS

§ 1191a.22. Patient and caregiver registry.

- (a) The Department will maintain a patient and caregiver registry.

- (b) Patient and caregiver information maintained by the Department is confidential and not subject to public disclosure, including disclosure under the Right-to-Know Law (65 P.S. § 67.101—67.3104). Patient and caregiver information must include the following:
- (1) Information provided in an identification card application.
  - (2) Information in a patient certification issued by a practitioner.
  - (3) Criminal history record check information provided as part of an identification card application submitted by a caregiver under § 1191 a.27 (relating to criminal background checks).
  - (4) Information encoded in the 2D barcode of an identification card.
  - (5) Information relating to a patient's serious medical condition.
- (c) A caregiver who is listed in the patient and caregiver registry may waive in writing the caregiver's right to confidentiality and consent to the caregiver's name and contact information being provided to a patient who has obtained a patient certification from a practitioner.

§ 1191a.23. Patients and caregivers generally.

- (a) The qualifications that a patient or caregiver shall meet to be included in the patient and caregiver registry and to obtain an identification card or a medical marijuana patient authorization letter are continuing qualifications.
- (b) Except with respect to a minor patient as provided in § 1191a.32 (relating to medical marijuana patient authorization letters), the Department may issue an identification card to an applicant who meets the qualifications in the act and this part.
- (c) 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.

- (d) A minor patient shall have a caregiver who is one of the following:
  - (1) A parent or legal guardian.
  - (2) An individual designated by a parent or legal guardian.
  - (3) An appropriate individual approved by the Department upon a sufficient showing that a parent or legal guardian is not appropriate or available.

§ 1191a.24. Medical marijuana cardholder responsibilities.

- (a) A medical marijuana cardholder shall immediately contact the Department upon the occurrence of any of the following:
  - (1) A change of the medical marijuana cardholder's name or address.
  - (2) The withdrawal of a patient certification by a practitioner under § 1181a.29 (relating to revocation of a patient certification).
  - (3) A decision by a patient or the patient's legal guardian to discontinue the services of a caregiver.
  - (4) A decision by a caregiver to no longer serve as a caregiver for a patient.
  - (5) A decision by a patient, the patient's legal guardian or a parent on behalf of a patient to discontinue obtaining medical treatment from the practitioner who issued the patient certification.
- (b) A medical marijuana cardholder shall apply to the Department for a replacement identification card within ten business days of discovering the loss or defacement of the identification card.

§ 1191a.25. Application for, and issuance or denial of, identification cards.

- (a) 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.
- (b) An identification card application submitted by or on behalf of a patient must include, at a minimum, the following information:
  - (1) The name, address, telephone number, e-mail address, if available, and date of birth of the patient.
  - (2) The patient's Pennsylvania driver's license number, a Department of Transportation State-issued identification card, if applicable, or other documentation acceptable to the Department evidencing the patient's identification and residency in this Commonwealth.
  - (3) The name, address and telephone number of the practitioner who issued the patient certification.
  - (4) The name, birth date, address, telephone number and e-mail address, if applicable, of up to two individuals designated by the applicant to serve as caregivers, if applicable.
  - (5) The patient certification issued by the patient's practitioner, which shall be provided by the practitioner to the Department under § 1181a.27(d)(2) (relating to issuing patient certifications).
  - (6) The appropriate fee or proof of financial hardship as provided for in § 1191a.26 (relating to application fees).

- (7) The signature of the applicant and the date signed.
  - (8) A statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).
  - (9) Any other information deemed necessary by the Department.
- (c) For an application submitted under this section that designates an individual as a caregiver who is not authorized under the act or this part to serve as a caregiver, the following apply:
- (1) The Department may deny that portion of the application and approve the balance of the application. In that case, an identification card may be issued to the patient but the designated caregiver will not be authorized to serve in that capacity.
  - (2) If the application is submitted on behalf of a minor patient but does not include the designation of another individual as a caregiver who is authorized under the act or this part to serve as a caregiver, the Department will deny the entire application unless and until the applicant designates an individual who is authorized to serve.
  - (3) An individual designated as a caregiver may not serve as a caregiver unless and until the individual submits an application under subsection (d) and the individual is issued an identification card by the Department.
- (d) An identification card application submitted by a caregiver must include, at a minimum, the following information:
- (1) The name, address, telephone number, e-mail address, if available, and date of birth of the caregiver.

- (2) The caregiver's Pennsylvania driver's license number, a Department of Transportation State-issued identification card, if applicable, or other documentation acceptable to the Department evidencing the caregiver's identification.
  - (3) The name, address and telephone number of the practitioner who issued the patient certification.
  - (4) The patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under § 1181a.27(d)(2).
  - (5) A copy of the criminal history record information required under § 1191a.27 (relating to criminal background checks).
  - (6) The name, address, telephone number and e-mail address, if available, of up to five patients for which the caregiver wishes to be approved by the Department as a caregiver.
  - (7) The appropriate fee or proof of financial hardship as provided for in § 1191a.26 (relating to application fees).
  - (8) The signature of the applicant and the date signed.
  - (9) A statement that a false statement made in the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49.
  - (10) Any other information deemed necessary by the Department.
- (e) The Department will review the criminal history record information obtained by a caregiver under § 1191a.27 and the Prescription Drug Monitoring Program database before approving the issuance of an identification card to the caregiver. The Department will deny the issuance of an identification card to a caregiver if the caregiver has been

convicted of a criminal offense relating to the sale or possession of drugs, narcotics or controlled substances that occurred within the five years immediately preceding the submission of the application. The Department may deny the issuance of an identification card to a caregiver if the caregiver has a history of drug abuse or of diverting controlled substances or illegal drugs.

- (f) The Department will promptly notify an applicant in writing if an identification card application is incomplete or factually inaccurate and provide the applicant with an explanation as to what documents or information are necessary for the Department to consider the identification card application to be complete and accurate.
- (g) An applicant shall have 60 days from receipt of a notification under subsection (f) to submit to the Department the documents or information requested. If an applicant fails to submit the requested documents or information within 60 days, the Department may deny the identification card application.
- (h) The Department will notify an applicant in writing of the reasons for the denial of an identification card application.
- (i) An applicant whose identification card application is denied may submit a new identification card application. The Department may decline to consider a new application that does not correct the deficiencies in the initial application leading to a prior denial.

§ 1191a.26. Application fees.

- (a) An applicant shall pay no more than one fee of \$50 in a 12-month period for an identification card with an identification card application.

- (b) Notwithstanding subsection (a):
  - (1) An applicant shall submit a fee of \$25 if the Department issues a replacement identification card as a result of a lost, stolen, destroyed, defaced or illegible identification card.
  - (2) An applicant shall pay a second fee of \$50 in the same 12-month period with an identification card renewal application.
- (c) The Department may establish higher fees for issuance of a second and subsequent replacement identification cards by publishing notice of those fees in the *Pennsylvania Bulletin*.
- (d) Subject to § 1191a.32 (relating to medical marijuana patient authorization letters), the Department may waive or reduce the fee for an identification card application or identification card renewal application for an applicant who demonstrates financial hardship. The Department will post on its publicly-accessible web site the qualifications for financial hardship that an applicant requesting a waiver or reduction of the application fee shall submit with an identification card application or identification card renewal application. The Department will publish notice of the qualifications for financial hardship in the *Pennsylvania Bulletin*.

§ 1191a.27. Criminal background checks.

- (a) An individual applying for an identification card to serve as a caregiver shall submit fingerprints to the Pennsylvania State Police, or an authorized agent, for the purpose of obtaining a criminal history record check. The Pennsylvania State Police, or an authorized agent, will submit the fingerprints to the Federal Bureau of Investigation for

the purpose of verifying the identity of the caregiver and obtaining a current record of any criminal arrests and convictions.

- (b) The Department may only review the criminal history record information received under subsection (a) to determine the caregiver's character, fitness and suitability to serve as a caregiver under the act and this part.

§ 1191a.28. Identification cards.

- (a) The Department will issue an identification card to a patient or caregiver as soon as reasonably practicable after approving an identification card application.
- (b) An identification card will contain all of the following information:
  - (1) The full name of the medical marijuana cardholder.
  - (2) The address of the medical marijuana cardholder.
  - (3) A designation of the medical marijuana cardholder as a patient or a caregiver.
  - (4) The date of issuance and the date of expiration of the identification card.
  - (5) A unique identification number for the medical marijuana cardholder.
  - (6) A photograph of the medical marijuana cardholder unless the patient or caregiver provides the Department with a statement in accordance with subsection (c).
  - (7) Any requirement or limitation on the patient certification concerning the recommended form of medical marijuana products or limitation on the duration of use, if applicable.
  - (8) Any other information deemed necessary by the Department.
- (c) Notwithstanding subsection (b)(6), the Department may not require a photograph on an identification card if a statement is provided to the Department in an identification card

application that a photograph cannot be provided due to religious beliefs.

- (d) An identification card issued to a patient will expire on the earlier to occur of the following:
  - (1) The date occurring one year from the date of issuance.
  - (2) The date, if any, contained in the patient certification issued to the patient beyond which the practitioner does not believe the use of medical marijuana by the patient would be therapeutic or palliative.
  - (3) The date the patient dies.
- (e) An identification card issued to a caregiver will expire on the earlier to occur of the following:
  - (1) The date that occurs one year from the date of issuance.
  - (2) Any of the events listed under subsection (d)(2) or (3).
  - (3) The date the caregiver dies.

§ 1191a.29. Renewing an identification card.

- (a) A medical marijuana cardholder shall submit an identification card renewal application to the Department no later than 30 days prior to the expiration date on the card. The form of the renewal application will be prescribed by the Department and will be made available on the Department's publicly-accessible web site and in hard copy upon request. If a medical marijuana cardholder's patient certification is expired, the cardholder shall obtain a new or updated patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under § 1181a.27(d)(2) (relating to issuing patient certifications).

- (b) If the Department denies an identification card renewal application or if the Department does not receive a complete identification card renewal application by the expiration date on the identification card, the identification card will no longer be valid beyond the expiration date and the Department may remove a medical marijuana cardholder from the patient and caregiver registry.

§ 1191a.30. Revocation or suspension of identification card.

- (a) The Department may revoke or suspend a medical marijuana cardholder's identification card upon the occurrence of any of the following:
  - (1) The Department receives written notice from a practitioner under § 1181a.29(a) (relating to revocation of a patient certification).
  - (2) A caregiver notifies the Department in writing that the caregiver is no longer acting as a caregiver.
  - (3) The patient or caregiver has intentionally, knowingly or recklessly violated the act or regulations as determined by the Department. The suspension or revocation will be in addition to any criminal or other penalty that may apply.
  - (4) Except for good cause shown, a medical marijuana cardholder does not visit a dispensary within 60 days from the issuance date on an identification card.
  - (5) A patient notifies the Department in writing that the patient has removed or changed a current caregiver. If the caregiver is not serving as a caregiver for any other patient, the Department will issue a notification to the caregiver that the caregiver's identification card is invalid and shall be promptly returned to the Department.

- (b) The Department will promptly notify a medical marijuana cardholder in writing of any action taken by the Department regarding the medical marijuana cardholder as a result of information received under subsection (a).
- (c) If a patient's practitioner's registration has been revoked or suspended under § 1181a.26 (relating to denial, revocation or suspension of a practitioner registration) or if a patient's practitioner withdraws the patient's patient certification under § 1181a.29(c), a medical marijuana cardholder shall obtain a new patient certification within 90 days of receiving written notice from the Department or prior to the expiration date on the identification card, whichever is sooner.

§ 1191a.31. Obtaining medical marijuana products from a dispensary.

- (a) A medical marijuana cardholder may only obtain medical marijuana products from a dispensary in accordance with § 1161a.24 (relating to limitations on dispensing).
- (b) A medical marijuana cardholder may only obtain medical marijuana products from a dispensary based upon the recommendation in a patient certification that has not been revoked under § 1181a.29 (relating to revocation of a patient certification) and that may be accessed by a dispensary through the electronic tracking system.

§ 1191a.32. Medical marijuana patient authorization letters.

- (a) The Department will issue a medical marijuana patient authorization letter to a minor patient instead of issuing an identification card to the minor patient. Upon reaching 18 years of age, a minor patient who has been issued a medical marijuana patient authorization letter will be entitled to receive an identification card upon application

under § 1191a.25 (relating to application for, and issuance or denial of, identification cards).

- (b) The Department may issue a medical marijuana patient authorization letter to an adult patient only when the patient's illness or infirmity permanently prevents the patient from visiting a dispensary.
- (c) A patient who has been issued a medical marijuana patient authorization letter by the Department under this section shall have all of the rights and obligations of a medical marijuana cardholder under this chapter, except that an identification card shall be required for entry into a dispensary.
- (d) A medical marijuana patient authorization letter is subject to the same terms and conditions, including expiration, revocation and suspension requirements, as an identification card under this chapter.
- (e) A patient who has been issued a medical marijuana patient authorization letter by the Department under this section will not be required to pay an identification card application fee or an identification card renewal application fee.

§ 1191a.33. Appeals.

Chapter 5, Subchapter A of 2 Pa.C.S. (relating to practice and procedure of Commonwealth agencies) and the accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

#### **CHAPTER 1211 (Reserved)**

**§§ 1211.21—1211.37 (Reserved).**

CHAPTER 1211a. CLINICAL REGISTRANTS AND ACADEMIC RESEARCH CENTERS

§ 1211a.22. Clinical registrants generally.

- (a) The qualifications that a clinical registrant shall meet to be approved by the Department are continuing qualifications.
- (b) An applicant that has already been issued a grower/processor permit or a dispensary permit by the Department under sections 601--616 of the act (35 P.S. §§ 10231.601--10231.616) who wishes to become an approved clinical registrant shall:
  - (1) Submit a request to the Department under § 1211a.28 (relating to request for conversion of an existing permit) with the application for approval of a clinical registrant.
  - (2) Not be required to apply for, or be eligible to receive, an additional grower/processor permit or dispensary permit under the act, this chapter, Chapter 1141a, Chapter 1151a or Chapter 1161a (relating to general provisions; growers/processors; and dispensaries), as applicable.
- (c) The Department will not approve more than eight clinical registrants.
- (d) An approved clinical registrant may not dispense or offer to dispense, as a clinical registrant, any medical marijuana products at the clinical registrant dispensary location until:
  - (1) The Department has determined that an approved clinical registrant is ready, willing and able to operate as a grower/processor and a dispensary.
  - (2) The approved clinical registrant demonstrates to the satisfaction of the

Department that it will be able to begin an approved research program or research study within six months following the date the Department determines the approved clinical registrant's dispensary to be operational.

- (e) An approved clinical registrant may dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee who is authorized to dispense medical marijuana products at a dispensary location operated by an approved clinical registrant under this chapter regardless of whether the patient is a participant in a research study.

§ 1211a.23. Limitation on permits.

- (a) An approved clinical registrant may not hold more than one grower/processor permit and one dispensary permit.
- (b) A dispensary permit held by an approved clinical registrant for use under this chapter may be used to dispense medical marijuana products at no more than six separate locations as approved by the Department, each of which shall be dispensing medical marijuana for the purpose of conducting research.
- (c) An approved clinical registrant may not locate more than three of its approved dispensaries in the same medical marijuana region or in the same county.

§ 1211a.24. Capital requirements.

An applicant shall provide all of the following information with its application under § 1211a.27 (relating to application for approval of a clinical registrant):

- (1) An affidavit, on a form prescribed by the Department, stating that the applicant

has at least \$15 million in capital, which must include evidence that the applicant meets the capital requirements of a medical marijuana organization under § 1141a.30 (relating to capital requirements).

- (2) A release sufficient to obtain information from a state governmental agency, financial institutions, an employer or any other person to verify the requirements of paragraph (1). Failure to provide a release will result in the rejection of the application for approval of a clinical registrant.

§ 1211a.25. Certifying ACRCs.

- (a) The qualifications that an ACRC shall meet to be approved by the Department are continuing qualifications.
- (b) An accredited medical school may file an application with the Department to be certified as an ACRC using a form prescribed by the Department. The Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of the application and the time period during which the Department will accept applications.
- (c) An application submitted under subsection (b) must include all of the following information:
  - (1) The legal name, address and telephone number of the accredited medical school and the name, telephone number and professional e-mail address of an individual at the accredited medical school who will be the primary contact for the Department during the Department's review of the application.
  - (2) The legal name, address and telephone number of the acute care hospital that is operated by or partnered with the accredited medical school and the name,

telephone number and professional e-mail address of an individual at the accredited medical school who will be the primary contact for the Department during the Department's review of the application.

- (3) An affidavit, on a form prescribed by the Department, disclosing any payments to the accredited medical school or any of its affiliates made by a person with whom the accredited medical school intends to enter into a research contract for purposes of operating as an approved clinical registrant or by any principal or financial backer of the person, up to and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.
  - (4) A statement that the accredited medical school is currently accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation.
  - (5) A statement that the acute care hospital designated by the accredited medical school under paragraph (2) holds a valid license from the Department.
  - (6) The State and Federal tax identification numbers of the accredited medical school.
  - (7) A statement that a false statement made by the accredited medical school submitting the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).
  - (8) Any other information deemed necessary by the Department.
- (d) The Department will publish a list containing the name and address of each ACRC on its publicly-accessible web site and in the *Pennsylvania Bulletin*.

§ 1211a.26. Revocation of a certification of an ACRC.

- (a) The certification of an ACRC will be revoked by the Department upon the occurrence of any of the following:
  - (1) The ACRC is no longer accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation, as applicable.
  - (2) The ACRC no longer operates or is partnered with the acute care hospital listed in its application for certification.
  - (3) The ACRC is no longer located in this Commonwealth.
- (b) If the Department intends to revoke the certification of an ACRC under this section, the Department will provide written notice of its intention to the ACRC. Upon receipt of a notice under this subsection, the ACRC shall have 90 days from the date of the notice to provide the Department with evidence satisfactory to the Department that it has received reaccreditation by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation, as applicable, that it operates or is partnered with another acute care hospital or that it has relocated within this Commonwealth. If the ACRC does not comply with this subsection within 90 days from the date of the notice, the Department may revoke the certification of the ACRC.

§ 1211a.27. Application for approval of a clinical registrant.

- (a) An applicant shall file an application for approval of a clinical registrant with the Department on a form prescribed by the Department. The Department will publish a notice in the *Pennsylvania Bulletin* announcing the availability of applications and the

time period during which the Department will accept applications.

- (b) An application for approval of a clinical registrant submitted under this section must include all of the following information:
- (1) The legal name, address and telephone number of the applicant and the name, telephone number and professional e-mail address of an individual who will be the primary contact for the Department during the Department's review of the application.
  - (2) The name of the ACRC under § 1211a.25 (relating to certifying ACRCs).
  - (3) The applicant's State and Federal tax identification numbers.
  - (4) An affidavit, on a form prescribed by the Department, disclosing any payments made by the applicant, a principal or financial backer of the applicant to an ACRC or any affiliates of an ACRC, up to and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.
  - (5) The name of an institution of higher education, if any, that will be participating in an approved research program or research study.
  - (6) An affidavit and release under § 1211a.24 (relating to capital requirements).
  - (7) Evidence that the applicant is responsible and capable of successfully operating as an approved clinical registrant, including all of the following:
    - (i) A copy of the research contract between the applicant and the ACRC.
    - (ii) A description of the research program or research study the applicant and the ACRC intend to conduct.
    - (iii) A statement that the applicant may not engage in the business of selling,

dispensing or offering to dispense medical marijuana products at an applicant's dispensary as a clinical registrant until the clinical registrant dispensary is ready, willing and able to dispense medical marijuana products.

- (8) Except as provided in § 121 1a.28 (relating to request for conversion of an existing permit), an application for a grower/processor permit under Chapters 1141a and 1151a (relating to general provisions; and growers/processors).
  - (9) Except as provided in § 121 1a.28, an application for a dispensary permit under Chapter 1141a and Chapter 1161a (relating to dispensaries).
  - (10) A statement that a false statement made by the applicant is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).
  - (11) Any other information deemed necessary by the Department.
- (c) An applicant may only include one ACRC in its application for approval of a clinical registrant.
  - (d) The following documents provided to the Department under this chapter are confidential and not subject to disclosure under the Right-to-Know Law (65 P.S. §§ 67.101--67.3104):
    - (1) A research contract.
    - (2) A description of a research program or research study.
    - (3) An ACRC's intellectual property.
    - (4) An approved clinical registrant's intellectual property.

§ 121 1a.27a. Research contracts.

- (a) An applicant for approval as a clinical registrant shall provide, with its application, either

an executed agreement or a letter of intent to enter into an agreement, with an ACRC, the effective date of which shall be on or after the effective date of the ACRC certification.

- (b) A clinical registrant applicant may submit more than one application, with separate applications identifying distinct ACRCs.
- (c) An ACRC may enter into a letter of intent with more than one clinical registrant applicant but may only execute a research contract with one approved clinical registrant.
- (d) If more than one applicant for approval as a clinical registrant submits an application that includes a letter of intent with the same ACRC, the Department shall follow the following process in approving the applications:
  - (1) Determine initially that the CR application meets the following qualifications:
    - (i) Is complete;
    - (ii) Complies with the act and this part, and
    - (iii) Meets the following minimum scoring requirements in each of the following application sections:

<i>Grower Processor Application</i>	<i>Max Points /</i>	<i>Minimum Acceptable</i>
	<i>Section</i>	<i>Score</i>
8--Operational Timetable	75	31
9--Employee Qualifications, Description of Duties and Training	25	11
10--Security and Surveillance	50	21
11--Transportation of Medical Marijuana	25	11
12--Storage of Medical Marijuana	25	11

13--Packaging and Labeling of Medical Marijuana	25	11
14--Inventory Management	25	11
15--Management and Disposal of Medical Marijuana Waste	25	11
16--Diversion Prevention	50	21
17--Growing Practice	100	41
18--Nutrient and Additive Practices	100	41
19--Processing and Extraction	100	41
20--Sanitation and Safety	25	11
22--Recordkeeping	25	11
24--Business History and Capacity to Operate	75	31
Attachment D: Site and Facility Plan	50	21
	<i>Max Points /</i>	<i>Minimum Acceptable</i>
<i>Dispensary Application</i>	<i>Section</i>	<i>Score</i>
8--Operational Timetable	100	41
9--Employee Qualifications, Description of Duties and Training	50	21
10--Security and Surveillance	100	41
11--Transportation of Medical Marijuana	50	21
12--Storage of Medical Marijuana	75	31
14--Inventory Management	75	31

15--Diversion Prevention	100	41
16--Sanitation and Safety	50	21
17--Recordkeeping	75	31
19--Business History and Capacity to Operate	75	31
Attachment D: Site and Facility Plan	50	21

(2) The Department shall approve clinical registrant applicants that meet the standards of paragraph (1) in the following order:

- (i) A clinical registrant applicant that holds a grower/processor permit and a dispensary permit, both of which are in good standing, and both medical marijuana organizations have been deemed operational by the Department. In applying this preference, the Department will look at the clinical registrant's primary dispensary location only.
- (ii) A clinical registrant applicant that holds a grower/processor permit only that is in good standing and the applicant's medical marijuana organization has been deemed operational by the Department.
- (iii) A clinical registrant applicant that holds a dispensary permit only that is in good standing and the applicant's primary dispensary location has been deemed operational by the Department.
- (iv) A clinical registrant applicant that holds a grower/processor permit only that is in good standing, but has not been deemed operational by the Department.
- (v) A clinical registrant applicant that holds a dispensary permit only that is in good standing, but has not had its primary location deemed operational by

the Department.

- (vi) A clinical registrant applicant that is applying for both a grower/processor permit and dispensary permit under this chapter. Awarding of approval to these clinical registrant applications shall be prioritized by ranking the sum of the grower/processor permit and dispensary permit application scores highest to lowest.

§ 1211a.28. Request for conversion of an existing permit.

- (a) An applicant holding a grower/processor permit or a dispensary permit, or both, under sections 601--616 of the act (35 P.S. §§ 10231.601--10231.616), shall submit a request for conversion of an existing permit under this section on a form prescribed by the Department when submitting an application for approval of a clinical registrant under § 1211a.27 (relating to application for approval of a clinical registrant).
- (b) Upon approval of a clinical registrant under subsection (a), the clinical registrant shall surrender its grower/processor permit or dispensary permit, or both, previously issued under sections 601--616 of the act.
- (c) A grower/processor permit or dispensary permit, or both, surrendered under subsection (b) will increase the number of grower/processor permits or dispensary permits, as applicable, available to other persons applying for permits under sections 601--616 of the act, Chapter 1141a (relating to general provisions) and Chapter 1151a or Chapter 1161a (relating to growers/processors; and dispensaries), as applicable.
- (d) An applicant may include additional dispensary locations in its request for conversion of an existing permit or may request additional dispensary locations at a later date under §

1161a.40 (relating to application for additional dispensary locations).

§ 1211a.29. Practices and procedures of research programs, projects or studies.

- (a) Medical marijuana dispensed as part of a research program shall be dispensed only in a form permitted by the act or this part and only from a dispensary to a patient or to a caregiver.
- (b) Marijuana dispensed under a research project or study may be dispensed, in any form deemed medically safe by an IRB, from a clinical registrant dispensary directly to an ACRC.
- (c) A RAC or IRB shall adopt research procedures and shall review and approve each research program in accordance with the RAC or IRB established practices and procedures.
- (d) An IRB shall review each proposed research project or study in accordance with the IRB's practices, procedures and protocols.
- (e) A RAC or IRB shall, at a minimum, ensure that each research program, project or study addresses all of the following:
  - (1) Protecting the rights and welfare of patients involved in research programs conducted under this chapter.
  - (2) Minimizing the risk to patients by using procedures that are consistent with sound research design and that do not unnecessarily expose patients to risk being performed on subjects for diagnosis or treatment purposes.
  - (3) Determining that the risks to patients involved in research programs are reasonable in relation to the anticipated benefits (if any) to the patients, and the

importance of the knowledge that may be expected to result from the research program.

- (4) Guaranteeing that informed consent will be sought from each prospective patient or the patient's legally authorized representative and is properly documented.
- (5) Protecting the privacy of every patient.

§ 1211a.30. Approval or denial of an application for approval of a clinical registrant.

- (a) An applicant shall be an approved clinical registrant upon the Department's approval of an application under § 1211a.27 (relating to application for approval of a clinical registrant).
- (b) The Department may deny the application for approval of a clinical registrant if the payments disclosed in the affidavit submitted under § 1211a.27(b)(4) violate the prohibition in § 1211a.34 (relating to prohibition).
- (c) Before the Department denies an application for approval of a clinical registrant under subsection (b), the Department will provide the applicant with written notice specifying the violation. The applicant may submit to the Department, within ten days following receipt of the Department's written notice, a supplemental affidavit indicating that the ACRC or its affiliate has refunded to the applicant or a principal or financial backer of the applicant that portion of payments in violation of § 1211a.34. Upon receipt of the supplemental affidavit, the Department may approve the application for approval of a clinical registrant. If the applicant fails to provide a supplemental affidavit within ten days of the Department's written notice, the Department will deny the application for approval of a clinical registrant.

- (d) An approved clinical registrant shall have the same rights and obligations as a medical marijuana organization that holds a grower/processor permit or a dispensary permit under sections 601--616 of the act (35 P.S. §§ 10231.601--10231.616) and Chapters 1141a, 1151a and 1161a (relating to general provisions; growers/processors; and dispensaries), as applicable, subject to any modifications or limitations in sections 2001--2003 of the act (35 P.S. §§ 10231.2001--10231.2003) and this chapter.
- (e) A grower/processor permit and a dispensary permit issued to an approved clinical registrant will expire upon the nonrenewal, revocation or suspension by the Department of the approved clinical registrant's approval.

§ 1211a.31. Renewal of approval of a clinical registrant.

- (a) The term of an approval of a clinical registrant will coincide with the term of the clinical registrant's grower/processor permit and dispensary permit.
- (b) An approved clinical registrant shall renew its approval as part of the renewal for a grower/processor permit and a dispensary permit under § 1141a.36 (relating to permit renewal applications). The renewal application must be on a form prescribed by the Department and include all of the following:
  - (1) A copy of the research contract.
  - (2) A list of the approved research programs or research studies that are continuing or, if any of them are concluded, the dates they were concluded.
  - (3) A report of the current status of active research programs or research studies being conducted under the research contract, including preliminary findings, if applicable, and any expectations and projections the approved clinical registrant

and the ACRC have for future research programs or research studies over the course of the two years following the date of submission of the report.

- (4) A description of proposed research programs or research studies covered by the research contract that the approved clinical registrant intends to conduct within the next year following submission of the renewal application including evidence of IRB approval for each research program or research study.
  - (5) A statement that a false statement made by the approved clinical registrant or the ACRC is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).
  - (6) Any other information deemed necessary by the Department.
- (c) The Department will not renew an approval for a clinical registrant under this section if the Department determines that none of the dispensary locations under the dispensary permit held by the approved clinical registrant are participating in an approved research program or research study and the approved clinical registrant does not intend to begin any additional approved research programs or research studies within the first six months following the approval of its application for renewal.

§ 1211a.32. Revocation of approval of a clinical registrant.

- (a) The approval of a clinical registrant will be revoked immediately by the Department upon the occurrence of any of the following:
  - (1) The Department revokes, suspends or does not renew the grower/processor permit or dispensary permit held by the approved clinical registrant.
  - (2) Subject to subsection (b), the Department revokes the certification of the ACRC

listed in the clinical registrant's application under § 1211a.27 (relating to application for approval of a clinical registrant).

- (3) The research contract between the approved clinical registrant and the ACRC expires without being renewed or is terminated by either party.
- (b) If the Department intends to revoke the certification of the ACRC under subsection (a)(2), the Department will provide written notice of its intention to the approved clinical registrant. Upon receipt of a notice under this subsection, the approved clinical registrant shall have 90 days from the date of the notice to contract with another ACRC that is not already a party to a research contract with another approved clinical registrant and to provide the Department with all relevant information relating to the ACRC. If the approved clinical registrant does not comply with this subsection within 90 days from the date of the notice, the Department may revoke the clinical registrant's approval.

§ 1211a.33. Dispensing and tracking medical marijuana products.

In addition to the information to be entered in the electronic tracking system under § 1161a.39 (relating to electronic tracking system) with respect to medical marijuana products dispensed to all patients and caregivers, the dispensary of an approved clinical registrant shall enter information into the electronic tracking system as required by the Department that identifies patients that are enrolled in an approved research program or research study.

§ 1211a.34. Prohibition.

Except for reasonable remuneration specifically in a research contract for the services to be performed or costs to be incurred by an ACRC, an ACRC may not solicit or accept anything of

value from an approved clinical registrant or a principal or financial backer of an approved clinical registrant. Reasonable remuneration may include up-front deposits or other payments to an ACRC under a research contract to defray start-up and ongoing costs of the ACRC in connection with the establishment of the contractual relationship in the research contract. This section does not apply to charitable contributions that are part of a history of giving to an ACRC established one year or more prior to the effective date of the act.

§ 1211a.35. Reporting requirements.

- (a) Except as provided in subsection (b), an approved clinical registrant shall provide a written report of the findings of its research program or research study to the Department within 365 days of the completion of an approved research program or research study.
- (b) In the event the approved clinical registrant or its ACRC intends to submit a manuscript of the results of an approved research program or research study to a peer-reviewed medical journal for publication, the written report required under subsection (a) shall be provided to the Department within 30 days following publication.
- (c) The Department may post the findings received under this section on its publicly-accessible web site and share them with other approved clinical registrants, ACRCs or any other person it determines would benefit from the findings.

§ 1211a.36. Sale or exchange.

- (a) The grower/processor of an approved clinical registrant may sell or exchange the following items to another grower/processor:
  - (1) Seeds.

- (2) Immature medical marijuana plants.
  - (3) Medical marijuana plants.
  - (4) Medical marijuana products.
- (b) The grower/processor of an approved clinical registrant may only sell its medical marijuana products to either its own approved dispensaries or any other approved dispensaries of an approved clinical registrant.
- (c) Notwithstanding subsection (b), an approved clinical registrant may petition the Department, on a form prescribed by the Department, to sell its medical marijuana products to a dispensary holding a permit under sections 601--616 of the act (35 P.S. §§ 10231.601--10231.616).
- (d) A petition filed under subsection (c) must include either the report or manuscript required under § 1211a.35 (relating to reporting requirements). If a clinical registrant fails to provide the report or manuscript required under § 1211a.35, the petition will be denied.

§ 1211a.37. Appeals.

Chapter 5 of 2 Pa.C.S. (relating to practice and procedure) and its accompanying regulations, as modified by Chapter 1230a (relating to practice and procedure), apply to actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

#### **CHAPTER 1230 [Reserved]**

**§§ 1230.21—1230.46 (Reserved).**

CHAPTER 1230a. PRACTICE AND PROCEDURE  
SUBCHAPTER A. PRELIMINARY PROVISIONS

GENERAL

§ 1230a.21. Scope.

- (a) This chapter governs practice and procedure before the Department in medical marijuana appeals and in any action taken by the Office under the act.
- (b) This chapter is not applicable to a proceeding to the extent that the applicable statute governing or authorizing the proceeding sets forth inconsistent practice or procedure.
- (c) Except when inconsistent with this chapter, 1 Pa. Code Part II (relating to General Rules of Administrative Practice and Procedure) is applicable insofar as it relates to adjudicatory proceedings.
- (d) Subsections (a)—(c) supplement 1 Pa. Code § 31.1 (relating to scope of part).

§ 1230a.22. Definitions.

- (a) The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Act—The Medical Marijuana Act (35 P.S. § § 10231.101—10231.2110).

Clerk—The Department’s Docket Clerk in the Office of Legal Counsel.

Department—The Department of Health.

Office—The Department’s Office of Medical Marijuana.

Person—An individual, partnership, association, corporation, political subdivision, municipal authority or other entity.

- (b) Subsection (a) supplements 1 Pa. Code § 31.3 (relating to definitions).

§ 1230a.23. Docket.

(a) The Clerk has the following duties:

(1) Provide information as to practice and procedure before the Department, under this chapter.

(2) Receive and docket pleadings and other documents required by the Department to be filed with the Clerk.

(b) A filing shall be directed to the Clerk at the following address, by first class mail, postage prepaid:

Department of Health Office of Legal Counsel ATTN: Docket Clerk Room 825, Health and Welfare Building 625 Forster Street Harrisburg, Pennsylvania 17120-0701

(c) Pleadings, submittals or other documents required or permitted to be filed under this chapter, the regulations of the Department or any other provision of law shall be received for filing by the Clerk within the time limits, if any, for the filing. The date of receipt by the Clerk and not the date of deposit in the mail is determinative. Electronic submissions will not be accepted by the Clerk for filing, unless the electronic filing is specifically permitted by the Department.

(d) The Clerk shall maintain a docket of proceedings. Each proceeding as initiated will be assigned a docket number.

(e) The docket will be available for inspection and copying by the public, at the requestor's expense, during the office hours of the Department insofar as consistent with the proper discharge of the duties of the Department.

- (f) Subsections (a)—(e) supersede 1 Pa. Code § § 33.11 and 33.51 (relating to execution; and docket).

§ 1230a.24. Filing generally.

- (a) Pleadings and other documents filed with the Clerk must clearly designate the docket number, if one has been assigned, the application or permit number, if one has been assigned, and a short title identifying the pleading or other document. The identity of the individual or person filing the pleading or other document, including the name, mailing address and status (for example, party or attorney for a party) must appear on the pleading or other document being filed.
- (b) If a pleading or other document tendered for filing does not comply with this chapter, does not sufficiently set forth required material or is otherwise deficient, the Department may decline to accept the pleading or other document for filing and may return it without filing, or the Department may accept the pleading or other document for filing and advise the individual or person tendering it of the deficiency and require that the deficiency be corrected within a reasonable period of time.
- (c) The Department may require redundant, immaterial, obscene or otherwise inappropriate comments stricken from a pleading or other document before accepting it for filing.

TIME

§ 1230a.25. Effective date of adjudication, actions or order.

- (a) An adjudication, action or order will be effective as of the date of mailing unless otherwise specifically provided.
- (b) Subsection (a) supersedes 1 Pa. Code § 31.14 (relating to effective dates of agency orders).

§ 1230a.26. Representation.

- (a) A party, except an individual appearing on his own behalf, shall be represented by an attorney at all stages of the proceedings subsequent to the filing of the Notice of Appeal or Order to Show Cause.
- (b) A corporation shall be represented by an attorney of record admitted to practice before the Supreme Court of Pennsylvania. A corporation may also be represented by an attorney in good standing and admitted to practice before the highest court of another State on a motion pro hac vice filed by the Pennsylvania attorney of record.
- (c) A group of individuals acting in concert, whether formally or informally, shall be represented by an attorney admitted to practice law before the Supreme Court of Pennsylvania or by an attorney in good standing admitted to practice before the highest court of another State who has made a motion to appear pro hoc vice and has agreed in that motion to abide by the rules and regulations of the Department and the Pennsylvania Rules of Professional Conduct.
- (d) An individual may appear in person on his own behalf. The individual is encouraged to appear through counsel. If the Department determines that the individual is acting in concert with or as a representative of a group of individuals, the individual may be required to appear through counsel under subsection (c).
- (e) Subsections (a)—(d) supersede 1 Pa. Code § § 31.21—31.23 (relating to appearance in person; appearance by attorney; and other representation prohibited at hearings).

SUBCHAPTER B. FORMAL PROCEEDINGS

APPEALS

§ 1230a.38. Commencement, form and content of Notice of Appeal.

- (a) An appeal from an action of the Office shall start with the filing of a Notice of Appeal with the Department.
- (b) The caption of a Notice of Appeal must be in the following form:

COMMONWEALTH OF PENNSYLVANIA

DEPARTMENT OF HEALTH

Name of Appellant	:	Docket No.: _____
Address of Appellant	:	
Telephone Number of Appellant,	:	
Appellant/Petitioner,	:	
v.	:	
	:	
The Pennsylvania Department of Health,	:	
	:	
Office of Medical Marijuana,	:	
Appellee/Respondent.	:	

NOTICE OF APPEAL

- (c) The Notice of Appeal must set forth the name, mailing address, e-mail address, permit number or application number, if one has been assigned, and telephone number of the appellant. If the appellant is represented by an attorney, the Notice of Appeal shall be signed by at least one attorney of record in the attorney’s individual name.
- (d) If the appellant has received written notification of an action of the Office, a copy of the action must be attached to the Notice of Appeal.

- (e) The Notice of Appeal must set forth in separate numbered paragraphs the specific objections to the action of the Office. The objections may be factual or legal.
- (f) The Notice of Appeal must be typewritten on letter-size paper (approximately 8 to 8 1/2 inches by 10 1/2 to 11 inches) and pages after the first must be numbered. Photocopies will be accepted as typewritten, provided that the copies are legible. Failure to comply with these requirements will not result in rejection or dismissal of the Notice of Appeal. The Department may request that the appellant file an amended version of the Notice of Appeal in proper form.
- (g) The appellant shall, concurrent with or prior to the filing of a Notice of Appeal, serve two copies on the Department's Office of Legal Counsel in the same manner in which the Notice of Appeal is filed with the Department.
- (h) Subsections (a)—(g) supersede 1 Pa. Code § § 35.5—35.7 and 35.20 (relating to informal complaints; and appeals from actions of the staff).

§ 1230a.39. Timeliness of Notice of Appeal.

- (a) Jurisdiction of the Department will not attach to an appeal from an action of the Office unless the Notice of Appeal is in writing and is timely filed with the Department within 30 days after the mailing date on the written notice of the action.
- (b) An untimely Notice of Appeal may be deemed an admission or may be dismissed with prejudice by the Department.
- (c) The Office may file an answer and new matter to the Notice of Appeal within 30 days of its service on the Office but is not required to do so.
- (d) Subsection (a) supersedes 1 Pa. Code § § 35.5—35.7, 35.20 and 35.35 (relating to

informal complaints; appeals from actions of the staff; and answers to complaints and petitions).

### SPECIAL ACTIONS

§ 1230a.43. Orders to Show Cause, orders or petitions filed by the Office.

- (a) The Office may start an action by filing an Order to Show Cause, order or other petition filed by the Office and a notice of a right to respond or defend. The action is begun when the Order to Show Cause, order or other petition of the Office is filed with the Clerk.
- (b) Service of the Order to Show Cause, order or other petition filed by the Office shall be by personal service or by United States first class mail, postage prepaid. The date of service shall be the date specified on the certificate of service.
- (c) An Order to Show Cause must set forth the authority under which the Department is authorized to act and must set forth in separate numbered paragraphs the specific facts and circumstances upon which the request for action is based.
- (d) The notice of a right to respond or defend shall conform substantially to the following:

[Case Caption]

### NOTICE

If you wish to defend against the claims set forth in the following pages, you must take action within thirty (30) days after this Order to Show Cause and notice are served by entering a written appearance personally or by attorney and filing in writing with the Clerk in accordance with § 1230a.23 your answers, defenses or objections to the claims set forth against you. You are warned that if you fail to do so, the case may proceed without you, and a judgment may be entered against you by the Department without further notice for

any claim or relief requested by the Office. You should take this paper to your lawyer at once.

- (e) Subsections (a)—(d) supersede 1 Pa. Code § 35.14 (relating to orders to show cause).

§ 1230a.44. Answers to Orders to Show Cause, orders or other petitions filed by the Office.

- (a) Answers to Orders to Show Cause, orders or other petitions filed by the Office shall be filed with the Clerk within 30 days after the date of service of the Order to Show Cause, order or other petition filed by the Office, unless, for cause, the Department, with or without motion, prescribes a different time.
- (b) Answers to Orders to Show Cause, orders or other petitions filed by the Office must set forth legal objections and any denial of facts in a single pleading.
- (c) Answers must be in writing and drafted as to fully and completely advise the parties and the Department as to the nature of the defense, including affirmative defenses. Answers must admit or deny specifically and in detail each material allegation of the Order to Show Cause, order or petition filed by the Office, and state clearly and concisely the facts and matters of law relied upon.
- (d) A Respondent failing to file an answer within the prescribed time will be deemed in default and, upon motion made as set forth in § 1232.46 (relating to entry of default judgment), all relevant facts in the Order to Show Cause, order or other petition filed by the Office may be deemed admitted, and default judgment may be entered.
- (e) New matter or preliminary objections may not be filed. To the extent that new matter or preliminary objections are filed, new matter or preliminary objections will be deemed stricken.

(f) Subsections (a)—(e) supersede 1 Pa. Code § 35.37 (relating to answers to orders to show cause).

§ 1230a.45. Verifications and affidavits.

- (a) Pleadings or other documents containing an averment of fact not appearing of record in the action or containing a denial of fact shall be personally verified by a party thereto or by an authorized officer of the party if a corporation or other business entity. Verification means a signed written statement of fact supported by oath or affirmation or made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities). If verification is required, notarization is not necessary.
- (b) The verification form must comply substantially with the following:

VERIFICATION

I, \_\_\_\_\_, hereby state that the facts above set forth are true and correct (or are true and correct to the best of my knowledge, information and belief). I understand that the statements herein are made subject to the penalties of 18 Pa.C.S. § 4904 (relating to unsworn falsification to authorities).

\_\_\_\_\_

Date

\_\_\_\_\_

Signature

\_\_\_\_\_

Printed Name

- (c) When an affidavit is used, the form should comply substantially with the following:

AFFIDAVIT

I, \_\_\_\_\_ (Affiant), being duly sworn (affirmed) according to law, depose and say that (I am authorized to make this affidavit on behalf of \_\_\_\_\_ corporation/business entity, being the holder of the office of \_\_\_\_\_ with that corporation/business entity, and that the facts above set forth are true and correct (or are true and correct to the best of my knowledge, information and belief).

\_\_\_\_\_

(Signature of affiant)

Sworn and subscribed before me this

\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_.

\_\_\_\_\_

(Signature of official administering oath)

§ 1230a.46. Entry of default judgment.

- (a) The Department, on motion of the Office, may enter default judgment against the Respondent for failure to file within the required time an answer to an Order to Show Cause, order or other petition allowed for under these regulations that contains a notice of a right to respond or defend.
- (b) The Respondent may answer the motion for default judgment and request a hearing. If a

request for a hearing on the default judgment is made, the Department may not grant default judgment prior to a hearing and the filing of an answer.

28 Pa. Code § 1151 Appendix A

§ 1151 Appendix A. Acceptable Pesticide Active Ingredients for Use

The following pesticides can be used legally in the growing and processing of seeds, immature medical marijuana plants, medical marijuana plants or medical marijuana and in accordance with the Pennsylvania Pesticide Control Act of 1973 (3 P.S. §§ 111.21-112). Products containing the following active ingredients must also be labeled for use in greenhouses on food crops to qualify.

<i>EPA Status</i>	<i>Pesticide Type</i>	<i>Comments</i>	<i>Active Ingredient</i>
25(b)	Insecticide		Castor Oil
25(b)	Insecticide		Cedar Oil
25(b)	Insecticide		Cinnamon
25(b)	Fungicide, Insecticide		Cinnamon Oil
25(b)	Fungicide, Insecticide		Citric Acid
25(b)	Bactericide, Fungicide		Clove
25(b)	Insecticide		Clove Oil
25(b)	Fungicide		Corn Oil
25(b)	Insecticide		Cottonseed Oil
25(b)	Insecticide		Garlic
25(b)	Insect Repellent		Garlic Oil
25(b)	Fungicide		Geraniol
25(b)	Insecticide		Geranium Oil
25(b)	Fungicide, Insecticide		Lemon Grass Oil

25(b)	Insecticide		Peppermint Oil
25(b)	Insecticide		Peroxyacetic Acid
25(b)	Fungicide		Potassium Sorbate
25(b)	Insecticide		Rosemary
25(b)	Insecticide		Rosemary Oil
25(b)	Fungicide, Insecticide, Miticide		Sesame Oil
25(b)	Fungicide, Insecticide		Sodium Lauryl Sulfate
25(b)	Insecticide		Soybean Oil
25(b)	Fungicide		Thyme
25(b)	Fungicide, Insecticide, Miticide		Thyme Oil
25(b)	Insecticide		White Pepper
Sec 3 Products	Insecticide		Azadirachtin
Sec 3 Products	Fungicide		Bacillus Amylolyticus Strain D747
Sec 3 Products	Fungicide	For use in protected growing environments only (for example, greenhouses).	Bacillus Pumilus Strain GHA 180
Sec 3 Products	Fungicide		Bacillus Subtilis QST713 Strain

Sec 3 Products	Insecticide		Bacillus Thuringiensis SSP. Aizawai
Sec 3 Products	Insecticide		Canola Oil
Sec 3 Products	Insect Repellent		Capsicum Oleoresin Extract
Sec 3 Products	Insecticide	Ground application only to nonblooming plants.	Chromobacterium Sub Strain PRAA4-1 Cells
Sec 3 Products	Fungicide, Insecticide		Clarified Hydrophobic Extract of Neem Oil
Sec 3 Products	Fungicide		Copper Octanoate
Sec 3 Products	PGR		Cytokinin (Kinetin)
Sec 3 Products	Insecticide		Diatomaceous Earth
Sec 3 Products	PGR		Gibberellins (Gibberellic Acid)
Sec 3 Products	PGR		Harpin Alpha Beta
Sec 3 Products	Antimicrobial, Fungicide	No foliar applications allowed.	Hydrogen Peroxide
Sec 3 Products	PGR	Applications allowed in furrow at planting or in hydroponics only.	IBA (Indole-3-Butyric Acid)
Sec 3 Products	Insecticide, PGR		Kaolin

Sec 3 Products	Insecticide		Mineral Oil
Sec 3 Products	Fungicide	Use only allowed prior to final transplant, unless grown in recirculating hydroponics systems.	Mono-Potassium and Di-Potassium Salts of Phosphorous Acid
Sec 3 Products	Insecticide		Monopotassium Phosphate
Sec 3 Products	Nematicide		Myrothecium Verrucaria
Sec 3 Products	Fungicide, Insecticide		Neem Oil, Cold Pressed
Sec 3 Products	Insecticide	Use allowed prior to final transplant.	Potassium Laurate
Sec 3 Products	Fungicide, Insecticide		Potassium Salts of Fatty Acids
Sec 3 Products	Insecticide		Pyrethrins
Sec 3 Products	Insecticide		Pyrethrins
Sec 3 Products	Molluscicide		Sodium Ferric EDTA
Sec 3 Products	Fungicide		Trichoderma Asperellum Strain ICC 012

<h2 style="margin: 0;">Regulatory Analysis Form</h2> <p style="margin: 0;">(Completed by Promulgating Agency)</p>		<p><b>INDEPENDENT REGULATORY REVIEW COMMISSION</b></p>
<p>(All Comments submitted on this regulation will appear on IRRC's website)</p>		
<p><b>(1) Agency:</b> Department of Health</p>		<p>IRRC Number:</p>
<p><b>(2) Agency Number:</b> 10-219 Identification Number:</p>		
<p><b>(3) PA Code Cite:</b> 28 Pa. Code §§ 1131, 1141, 1141a, 1151, 1151a, 1161, 1161a, 1171, 1171a, 1181, 1181a, 1191, 1191a, 1211, 1211a, 1230, 1230a</p>		
<p><b>(4) Short Title:</b> Medical Marijuana Regulations</p>		
<p><b>(5) Agency Contacts (List Telephone Number and Email Address):</b>                  Primary Contact: John J. Collins, (717) 547-3047 <a href="mailto:RA-DHMMregulations@pa.gov">RA-DHMMregulations@pa.gov</a>                  Secondary Contact:</p>		
<p><b>(6) Type of Rulemaking (check applicable box):</b></p> <p><input checked="" type="checkbox"/> Proposed Regulation  <input type="checkbox"/> Final Regulation  <input type="checkbox"/> Final Omitted Regulation</p>		<p><input type="checkbox"/> Emergency Certification Regulation;  <input type="checkbox"/> Certification by the Governor  <input type="checkbox"/> Certification by the Attorney General</p>
<p><b>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</b></p> <p>The Medical Marijuana Program (Program) was created by the Medical Marijuana Act (35 P.S. §§ 10231.101 - 10213.2110) (the act), which became effective on May 17, 2016. Under the act, persons, including minors under the age of 18, with a serious medical condition, may, either themselves or through a caregiver, purchase medical marijuana within the Commonwealth. In order to implement the Program, the Department of Health (Department) periodically published temporary regulations relating to various sections of the act, which are effective for two years from the date of publication are to be followed by the promulgation of formal permanent regulations. The most recent set of temporary regulations are set to expire November 20, 2021, and the Department now seeks to promulgate the permanent regulations to replace the current temporary regulations.</p> <p>In this proposed rulemaking, the Department is proposing slight amendments to the current temporary regulations to clarify those existing regulations and maintain proper regulation commensurate with the evolution of the Program.</p>		
<p><b>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</b></p>		

The Department's authority to promulgate these regulations is found in Section 301(b) of the act, which provides that the Department has the authority to promulgate all regulations necessary to carry out the provisions set forth in the act. (35 P.S. § 10231.301(b)).

**(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.**

The act required the Department to issue temporary regulations necessary to achieve the act's purpose within a particular time frame. The act provides that those temporary regulations would expire within two years of publication in the *Pennsylvania Bulletin*, and that all future regulations must be promulgated through the regulatory process set out in law. 35 P.S. § 10231.1107(b). Regulations are necessary for compliance with, and enforcement of, the act.

There are no relevant state or federal court decisions relating to these regulations

**(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.**

These proposed permanent regulations are necessary for the continued viability of the Program established by the act. Replacing the current temporary regulations—which are set to expire on November 20, 2021—with the proposed regulations would ensure that participants in the Program will continue to receive medicine and the Department would be able to continue to monitor and regulate the Program, as required by the act.

Beyond the timing requirement, these proposed regulations are needed so that the regulatory scheme may keep pace with the evolution of the Program. Since the act was signed into law on April 17, 2016, the Program has undergone two separate application and permitting phases for medical marijuana organizations. During this time, the Department has experienced consistent growth in the number of patients and medical marijuana organizations that participate in the Program. The revised and additional provisions in the proposed permanent regulations reflect the Department's efforts to keep pace with the growth and evolution of the program.

Those benefitting from these proposed regulations include any participant in the Program. As these proposed regulations ensure the continued viability of the Program, all participants benefit from this proposed rulemaking.

Medical marijuana patients would benefit from these proposed permanent regulations by being able to continue to receive medication to treat their serious medical conditions. Further, through the proposed permanent regulations, practitioners are prohibited from charging an excessive fee in providing this service. Medical marijuana caregivers would also benefit, as they are able to continue to provide their services to those medical marijuana patients who rely on the assistance of caregivers. Currently, there are nearly 39,000 registered caregivers, and nearly 296,000 active patients.

Further, the expected growth of the Program should result in increased competition amongst medical marijuana organizations, which may result in reduced product costs for cardholders. The Department is

continuing to gather data on the impact of the Program, including on costs and increase in capacity, and is expecting program and product expansion, as more growers/processors operationalize.

Medical marijuana practitioners would benefit from these regulations through the continued ability to provide certifications to patients with qualifying medical conditions who, in the practitioner's professional opinion, would benefit from the use of medical marijuana. Practitioners also typically charge a fee for their consultations with patients to certify them to participate in the Program. There are currently over 1,500 approved practitioners.

Medical marijuana organizations (dispensaries and grower/processors) and their employees would benefit through the continued viability of the program, as a medical marijuana organization's existence depends on the program. These organizations would be able to continue to conduct business within the parameters of the act and regulations. There are currently 56 dispensary permittees, including the eight clinical registrants under Chapter 20 of the act (relating to research), with each dispensary permittee permitted to have up to three dispensary locations (up to six in the research arena), and 32 grower/processor permittees, also including research permit holders. The number of people employed by medical marijuana organizations is unknown.

In addition, the proposed regulations provide for the implementation of a research program, that allows for the approval of eight clinical registrants and academic clinical research centers and permits them to carry on research. The ability to do research on medical marijuana, and the Commonwealth is the only state that has a research component to its medical marijuana program, will ultimately provide valuable data on the use of medical marijuana and its efficacy. This ultimately will benefit patients, and the Commonwealth, since enabling patients to more effectively deal with serious medical conditions should have a benefit both to the health care system, and to the overall social and economic wellbeing of the state.

**(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.**

There are no federal standards that relate to these proposed regulations.

**(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?**

Thirty-five other states and the District of Columbia have statutes permitting the use of medical marijuana. The Medical Marijuana Programs in those other states are largely the same as Pennsylvania's, providing processes for the growth, processing, dispensing, and purchasing of medical marijuana and medical marijuana products. One notable difference between programs established in

other states and Pennsylvania's program is that Pennsylvania is the only state that has established a research program for medical marijuana. This makes Pennsylvania's program unique and potentially the source of significant data regarding the use and efficacy of medical marijuana. This could be a significant benefit for those entities that are chosen to participate in the program as a clinical registrant or academic clinical research center, since it is expected that the results of the research may inform new products and lead to additional research and development in the area of medical marijuana. This may work to attract businesses and persons to the Commonwealth to participate in those studies.

With respect to medical marijuana organizations, many of the other states with medical marijuana programs issue permits to entities that dispense, grow and process or manufacture medical marijuana for medical treatment purposes. The industry is fairly rigorously regulated in most states. Therefore, most entities choosing to apply for a permit in the Commonwealth have dealt with similarly regulated states or would be subject to similar regulation in other states.

**(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.**

No, these changes will not affect any other regulations of the promulgating agency or other state agencies. By law the Department's temporary regulations relating to the Medical Marijuana Program will expire on November 20, 2021.

**(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)**

The Department requested input throughout the temporary regulation drafting process, including regarding changes to the regulations, by surveying different groups of stakeholders, including permittees, approved laboratories, caregivers and patients. The Department has also previously published each set of temporary regulations on its website and taken public comment. The evolution of these proposed regulations has come about, in part, as a result of those discussions and feedback.

The revisions to the temporary regulations set forth in the proposed permanent regulations are necessary to ensure consistency throughout the proposed regulations, and to ensure that the proposed regulations provide the necessary regulatory framework for continued program development and success. In addition, the implementation of the Program through the temporary regulations led to continuing discussions with patients, caregivers, growers/processors and dispensaries, and recommendations and comments about how the Program could better serve those stakeholders. The Department is offering these proposed permanent regulations, having taken into account some of those comments and recommendations, in order to ensure a safe and effective Program, how persons with serious medical conditions using medical marijuana in the Commonwealth could be sure that they were receiving a safe and effective product.

**(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?**

No Department of Labor standards apply to medical marijuana organizations, the Department cannot say with certainty whether any dispensary or grower/processor qualifies as a small business. Whether or not any of these regulated entities is a small business, however, the Department has not and would not consider less stringent requirements than those offered in these proposed permanent regulations. The Department's need for strict oversight is driven by the nature of the Program, and the possibility of federal enforcement reaching into the state were it to appear that requirements ensuring the safety and security of medical marijuana and medical marijuana products being grown, shipped and produced by these regulated entities were lax. It is the Department's responsibility to ensure the safety, security, and effectiveness of the Program, which it does by monitoring through its regulations.

The proposed permanent regulations apply to dispensaries, which is a type of business that has only legally existed in the Commonwealth since the act's inception. There are currently 56 dispensary permits issued by the Department, including those in the research arena. There are no current statewide standards that apply to this type of business entity to determine what would constitute a small business, and the Department has no way of making that determination, since it does not maintain information on the numbers of employees each dispensary employs. These proposed permanent regulations mirror in large part the temporary regulations under which dispensaries are currently operating, so that the promulgation of these proposed permanent regulations should have little effect.

The proposed permanent regulations also apply to growers/processors, which is also a type of business that has only legally existed in the Commonwealth since the act's inception. There are currently 32 grower/processor permits issued by the Department, including permits in the research arena. Again, there are no statewide standards allowing a definition of small business to be developed in this context, the Department does not keep information on the number of employed at each grower/processor, and there are no federal requirements that can be applied. These proposed permanent regulations mirror in large part the temporary regulations under which growers/processors are currently operating, so that the promulgation of these proposed permanent regulations should have little effect.

The proposed permanent regulations apply to laboratories who choose to be certified by the Department to test medical marijuana and medical marijuana products by the Department. Laboratories are not required to participate in the Program. There are currently seven approved laboratories in the Commonwealth. These proposed permanent regulations mirror in large part the temporary regulations under which laboratories are currently operating, so that the promulgation of these proposed permanent regulations should have little effect.

The proposed permanent regulations also apply to a clinical registrant (CR), each of which holds a grower/processor permit and a dispensary permit. Those entities are discussed above as growers/processors and dispensaries. The proposed regulations also apply to a certified academic clinical research center (ACRC), which are educational institutions with medical schools. There are eight CRs and eight certified ACRCs in the Commonwealth. The Department may approve no more than eight CRs under the act. The proposed permanent regulations allow for the implementation of the research program, which would be unable to go forward without regulation.

The proposed regulations also apply to medical marijuana cardholders, which include both patients and caregivers. Medical marijuana patients and caregivers are required to comply with these proposed

regulations in order to receive medication to treat their or their patient's serious medical conditions. Failure to comply with the proposed regulations could cut off the patient's or caregiver's access to a medication that could be helpful in treating the patient's serious medical condition. As of February 1, 2021, just short of the third anniversary of the first-time medical marijuana was dispensed in the Commonwealth, there were nearly 39,000 registered caregivers, and nearly 296,000 active patients. These proposed permanent regulations mirror in large part the temporary regulations under which the Program is currently operating, so that the promulgation of these proposed permanent regulations should have little effect on patients and caregivers. Fees associated with obtaining medical marijuana identification cards would remain the same (\$50 annually), and the proposed regulations would continue to provide for fee reductions for those showing financial hardship (\$25 annually). However, the proposed permanent regulations provide that practitioners may not charge patients an excessive fee for services related to the patient becoming certified for medical marijuana use.

The regulations also apply to practitioners. Physicians must comply with the proposed regulations in order to become practitioners able to certify patients so that the patient can obtain medical marijuana to treat the patient's serious medical condition. In addition to enabling physicians to become practitioners, and participate in the Program, the proposed regulations also ensure that physicians who become practitioners have had the appropriate training and are able to safely and effectively treat and monitor patients. They also enable the Department to monitor practitioners, and to take the necessary action to ensure a safe and effective Program. As of February 1, 2021, there were over 1,500 approved practitioners. These proposed permanent regulations mirror in large part the temporary regulations under which practitioners are currently certifying patients, so that the promulgation of these proposed permanent regulations should have little effect on their practice. The proposed permanent regulations do provide that practitioners may not charge patients an excessive fee for services related to the patient becoming certified for medical marijuana use, which does allow for additional action to be taken against practitioners by the Department, in coordination with the Department of State, in the event of a complaint regarding fees.

These proposed regulations also apply to the employees of the dispensaries, growers/processors and laboratories covered by the regulations, including other medical professionals employed by the dispensaries, like physicians' assistants and certified registered nurse practitioners. Although the Department does not have direct control over employees and medical professionals, except to require background checks in certain instances, the proposed regulations set standards for the operation of dispensaries and growers/processors. The proposed regulations enable the Department to require effective operations and safe and effective growth, production, sales and dispensing of medical marijuana and medical marijuana products. The Department does not have information on the number of these employees that exist. Again, since the proposed permanent regulations do not change extensively the requirements in the temporary regulations, there should be little effect on the manner in which employees of these entities operate.

Finally, the proposed regulations would apply to any future participant in the Program. The effect on these groups of participants would be the same as explained above in this response.

**(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.**

Every group of individuals and entities listed in the response to Question 15 is required to comply with this proposed rulemaking. No Department of Labor standards apply to medical marijuana organizations,

the Department, therefore, cannot say with certainty whether any dispensary or grower/processor qualifies as a small business.

With respect to medical marijuana organizations, there are currently 56 dispensary permittees, including those in the research arena, with each dispensary permittee permitted to have up to three dispensary locations (up to six in the research arena), and 32 grower/processor permittees, also including research permit holders.

There are currently eight accredited medical schools certified as ACRCs. Eight CRs have been approved to date.

Any laboratory that wishes to participate in the Program will be required to comply with these regulations. At the current time, the Department has approved seven laboratories to do testing. The act does not place a limitation on the number of laboratories that may participate, and the Department continues to review laboratory applications.

Medical marijuana patients and caregivers are required to comply with these proposed regulations in order to receive medication to treat their or their patient's serious medical conditions. This number changes frequently. As of February 1, 2021, just prior to the third anniversary of the first dispensing of medical marijuana in the Commonwealth, nearly 296,000 active patients participate in the Program, and nearly 39,000 caregivers have registered.

There were over 2,000 physicians registered as practitioners as of February 1, 2021, over 1,500 of which were approved. The act does not place a limit on the number of physicians that may apply to become practitioners.

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**(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.**

The proposed regulations allow medical marijuana organizations to continue to exist and operate legally within the Commonwealth. While the Program is currently operating at nearly the statutory capacity for permits, should additional permits become available in the future, the fees included in the statute with respect to growers/processors would remain the same: applicants for a grower/processor permit would be required to pay a non-refundable application fee of \$10,000 and a refundable permit fee of \$200,000, in the event a permit is not awarded. They are also required, by statute, to have \$2,000,000 in capital, \$500,000 of which must be on deposit at a financial institution. With respect to dispensaries, the requirements that are set out in statute also remain the same; dispensary applicants are required to pay a non-refundable initial application fee of \$5,000 and a refundable permit fee of \$30,000 for each dispensary location, again, in the event a permit is not awarded. Permit renewal fees are \$10,000 and \$5,000 annually for growers/processors and dispensaries, respectively.

With respect to medical marijuana cardholders, fees associated with obtaining medical marijuana identification cards would remain the same (\$50 annually), and the proposed regulations would provide for fee reductions for persons showing financial hardship (\$25 annually). The proposed permanent regulations provide that practitioners may not charge a patient an excessive fee for services related to the patient becoming certified for medical marijuana use.

Further, the expected growth of the Program should result in increased competition amongst medical marijuana organizations, which may result in reduced product costs for cardholders. The Department is continuing to gather data on the impact of the Program, including on costs and increase in capacity, and is expecting program and product expansion as more growers/processors operationalize.

The social impact of the Program on individuals using medical marijuana products is still anecdotal due to the fact that the Program has only been providing medical marijuana to the public for two years. The research component of the Program has not yet become operational. The Department is in the final stages of approving CRs and is hopeful that the research done by the ACRCs and CRs will provide valuable data on the use of medical marijuana and its efficacy.

**(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.**

These proposed regulations would benefit those participating in the Program by ensuring that medical marijuana patients would continue to receive the medicine provided by medical marijuana organizations. As the current temporary regulations are set to expire on November 20, 2021, the primary benefit of the proposed permanent regulations is that they are necessary to maintain the regulatory scheme of the Program. Without regulations, the regulatory scheme laid out in the act, while sufficient to broadly oversee the production, sale, and dispensing of medical marijuana, lacks the specificity to fully ensure that there would be no concerns over safety and consistency of the products produced and the manner in which the product is dispensed and sold.

The Department must ensure that the Program satisfies the concerns of federal law enforcement that medical marijuana is strictly regulated and that the production, sale, dispensing and use is strictly controlled in order to prevent diversion for improper use. The creation through temporary regulations and continuation of strict regulatory requirements in the proposed permanent regulations, along with strict enforcement procedures, would allow the Department to satisfy these concerns. The cost to participants in the Medical Marijuana Program associated with the implementation of a detailed and strict permitting program therefore, is be outweighed by the need to ensure that the Program is a safe and effective Program, providing an effective and sage medical tools to treat patients with serious medical conditions.

As of August 5, 2020, the Department has approved the statutory maximum number of clinical registrants (8) as part of the research portion of the Program. As Pennsylvania is the only state that has established a research program for medical marijuana, the benefit of successful applicants to research further benefits of medical marijuana provides a benefit to not only citizens of the Commonwealth, but the medical marijuana industry as a whole, as information relating to differing strains, doses, and the best ways to use medical marijuana will be studied. This will allow for production of the most effective strains. It will also allow the most effective recommendations and dosing for patients and allow them to gain the most benefit from the use of this medicine.

**(19) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.**

The costs provided in the current temporary regulations would be unchanged by the proposed permanent regulations. Below are the associated costs for the various groups of participants in the Medical Marijuana Program.

### **Patients and Caregivers**

Patients and caregivers would be assessed a \$50 fee for an identification card application and an identification card renewal application and a \$25 fee for an identification card replacement. These requirements are statutory and were included in the temporary regulations that the Department implemented as required by the act. The Department can raise the replacement fee for a second and subsequent replacement cards and may alter that fee upon publication of notice in the *Pennsylvania Bulletin*. Further, the act provides that the Department may also waive an identification card application fee if the individual can demonstrate financial hardship. The act requires caregivers to undergo a background check. This is associated with minimal cost of approximately \$21.00. Again, these requirements were included not only in the act, but in the Department's temporary regulations.

### **Practitioners/Medical Professionals**

Practitioners must register to become approved to recommend medical marijuana to patients, but at no cost to practitioners.

### **Grower/Processors**

While the Program is currently operating near statutory capacity for permits, should additional permits become available in the future, growers/processors would be required to pay an initial application fee of \$10,000.00, and a permit fee of \$200,000.00, as required by the act. The initial application fee is not refundable; if the applicant does not receive a permit, the permit fee is refundable. The act requires that a grower/processor must also pay a renewal fee each year of \$10,000.00. It is refundable if the renewal is not granted. An application fee of \$250.00 is statutorily required if the grower/processor requests permission from the Department to change its location. All of these requirements were included in the act, and in the Department's temporary regulations, echoing those statutory requirements.

In addition, any new growers/processors in the future would need to obtain zoning and, in some cases, building approvals, construct or renovate facilities, and put into place surveillance and security systems that meet certain standards set out in the proposed regulations, as would those seeking to change location and making building renovations. Existing growers/processors have already incurred these costs, as they became operational under the Department's temporary regulations; these proposed permanent regulations change very little from the temporary regulations relating to security and surveillance, although they would make certain revisions for the sake of clarity and consistency. In addition, the requirements in the proposed permanent regulations that growers/processors hire and train staff and maintain a fleet of transportation vehicles that meet certain standards are altered very little from the temporary regulations; for the most part these costs have already been incurred, except for the training of new staff and the purchase of new vehicles.

The proposed permanent regulations would not alter the statutory requirement that growers/processors are required to purchase and install electronic tracking systems prescribed by the Department. This cost has already been incurred by existing growers/processors.

These proposed regulations would not alter the statutory requirement that growers/processors would be required to purchase seed and plants to commence operations. This cost has already been incurred by existing growers/processors.

### **Dispensaries**

While the Program is currently operating near statutory capacity for permits, should additional permits become available in the future, dispensaries would be required to pay an initial application fee of \$5,000, and a permit fee of \$30,000 for each dispensary location, as is required by statute. The initial application fee would not be refundable; however, if the applicant does not receive a dispensary permit, the permit fee would be refundable. A dispensary must also pay a renewal fee each year of \$5,000, which is refundable if the permit renewal is not granted. An application fee of \$250.00 would be required if the dispensary seeks permission from the Department to relocate its operation.

In addition, any new dispensaries in the future would need to obtain zoning and, in some cases, building approvals, construct or renovate facilities, and put into place surveillance and security systems that meet certain standards set out in the proposed regulations, as would those seeking to change location and making building renovations. Existing dispensaries have already incurred these costs, as they became operational under the Department's temporary regulations; these proposed permanent regulations change very little from the temporary regulations relating to security and surveillance, although they would make certain revisions for the sake of clarity and consistency.

These proposed regulations would not alter the statutory requirement that dispensaries must purchase and install electronic tracking systems that meet the requirements of the act and regulations, a cost that has already been incurred by existing dispensaries.

### **Laboratories**

The proposed regulations do not require laboratories to pay an application fee but do require that they file an application with the Department in order to be approved to test medical marijuana. In order to be eligible for approval, a laboratory would be required to have an accreditation from an accrediting body whose accreditation is accepted by the Department. Accrediting bodies do charge a fee to a laboratory for the accreditation, and there is a cost to obtaining the accreditation and maintaining it. One accrediting body estimates the costs to a laboratory to be approximately \$50,000.00 per year. These costs include maintaining the equipment to meet certain calibration standards, and the cost of auditing results. In addition, laboratories that choose to participate in the Program, and are approved to do so by the Department, are paid by growers/processors to perform the testing through contractual arrangements, offsetting some or all of the laboratory's cost of obtaining and maintaining accreditation.

In addition, any new laboratory seeking approval of an application, that does not already have a physical presence in the Commonwealth would need to obtain zoning and, in some cases, building approvals, and construct or renovate existing property to be able to provide the testing services. A new laboratory would have to purchase equipment, hire staff and have staff trained. In order to comply with the proposed regulations, laboratories that choose to participate and seek approval may have to hire staff, have staff trained, or purchase equipment to do the required testing. If a laboratory does not wish to participate in the program, however, there is no requirement that it do so. These costs are voluntarily undertaken in order to take advantage of a potential business opportunity. This is no change from the temporary regulations that previously applied to laboratories wishing to participate in the Program.

### **Clinical Registrants/Academic Clinical Research Centers**

The proposed permanent regulations, like the temporary regulations, imposed no cost for an entity to apply to become an ACRC. The proposed permanent regulations would make no changes to the costs associated with CRs. There is no cost to apply to become an approved CR. However, the act requires that approved CRs pay the same permit fees to obtain a grower/processor permit and a dispensary permit as growers/processors and dispensaries that applied for a permit under sections 601-616 of the act. (35

P.S. §§ 10231.601-616). Under the act, a grower/processor is required to pay an initial application fee of \$10,000, an initial permit fee of \$200,000, and a renewal fee of \$10,000. A dispensary is required to pay an initial application fee of \$5,000, an initial permit fee of \$30,000 for each location and a renewal fee of \$5,000 that covers all locations.

**(20) Provide a specific estimate of the costs and/or savings to the local governments associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.**

These proposed regulations do not alter the statutory requirement that medical marijuana organizations comply with local zoning laws. In the event that a new medical marijuana organization were to seek zoning approval from a local government, or to move location, or a laboratory sought to perform services, local governments would be required to review those applications pursuant to local zoning ordinances. This could potentially lead to revenue from application fees, as well as costs associated with review of and litigation challenging these zoning decisions. Presumably, however, zoning matters are built into budgets of local governments. There is no way to estimate this type of cost.

**(21) Provide a specific estimate of the costs and/or savings to the state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.**

The Department has incurred and would continue to incur costs incident to hiring staff to administer and regulate the Program as it goes forward. This includes reviewing, and approving, applications for approval of a clinical registrant, applications for approval of an academic clinical research center, applications for a grower/processor permit, applications for a dispensary permit, applications for identification cards; operating and maintaining a patient and caregiver registry; monitoring the applications of patients and caregivers; and operating and maintaining a seed-to-sale electronic tracking system. To the extent an individual or entity chooses to appeal a denial of an application, the Department has incurred and would continue to incur legal costs.

The Department's costs are part of the program operations costs listed in section 23(a) below.

**(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.**

The proposed regulations include requirements for applications, forms, reporting and recordkeeping that are substantially similar to those included in the Department's temporary regulations, and that have been complied with by the regulatory community since the implementation of the Program:

#### **Patients/Caregivers**

The proposed regulations continue to require that, in order to be registered as a patient or caregiver and to receive an identification card, or to receive a medical marijuana patient authorization letter, an individual must complete an electronic application that is a part of the Department's patient and caregiver registry. The online patient registration form can be found here:

<https://padohmmp.custhelp.com/app/adult-patient-registration/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZlU3d3N>

[ZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINhlzVko5SmRHUUXITW1vQjFybXFIQIB5U1ZWX116TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D](https://padohmmp.custhelp.com/app/adult-patient-caregiver-registration/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZIU3d3NZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINhlzVko5SmRHUUXITW1vQjFybXFIQIB5U1ZWX116TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D).

The online caregiver registration form can be found here: <https://padohmmp.custhelp.com/app/adult-patient-caregiver-registration/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZIU3d3NZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINhlzVko5SmRHUUXITW1vQjFybXFIQIB5U1ZWX116TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D>. In addition, a caregiver would still be required to obtain a background check by applying for a background check in accordance with the act.

After successfully registering, a medical marijuana patient or caregiver must then apply for a medical marijuana identification (ID) card. The application for the ID card is done through the same sign-on site as the application for registration listed above. The ID card would be valid for one year from the time of issuance. The ID card or medical marijuana patient authorization letter must be renewed each year through a similar application process.

Further, the proposed regulations would provide that patients and caregivers have an obligation to contact the Department upon the occurrence of any of the following: (1) a change in the cardholder's name or address; (2) the withdrawal of a patient certification by a practitioner; (3) a decision by a patient or the patient's legal guardian to discontinue the services of a caregiver; (4) a decision by a caregiver to no longer serve as a caregiver for a patient; and (5) a decision by a patient, the patient's legal guardian or a parent on behalf of a patient to discontinue obtaining medical treatment from the practitioner who issued the patient certification.

These requirements are the same as in the temporary regulations.

### **Practitioners/Medical Professionals**

Practitioners who will issue patient certifications and medical professionals who will work in dispensaries are also required to register and be approved by the Department. The online practitioner registration form can be found here:

<https://padohmmp.custhelp.com/app/register/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZIU3d3NZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINhlzVko5SmRHUUXITW1vQjFybXFIQIB5U1ZWX116TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D>.

The online registration form for medical professionals can be found here:

<https://padohmmp.custhelp.com/app/medicalprof-register/session/L3RpbWUvMTU1NTM1ODgzNy9nZW4vMTU1NTM1ODgzNy9zaWQvZIU3d3NZaHJQZEdwRmw4NmhJU2ZqOE9Qc2dubEJRQ1glN0VuMUR4bWZoSkxXZXhaclpR3ljOFJmRnZMVUNVT0VINhlzVko5SmRHUUXITW1vQjFybXFIQIB5U1ZWX116TTdwaDdYWSU3RXYxcHdKZWtQOGxQbVE4TXR0QSUyMSUyMQ%3D%3D>.

The proposed permanent regulations would require that registered practitioners provide the Department with the patient certification with original signature after certifying a patient, as well as notifying the Department of any subsequent modifications to a patient certification. Further, practitioners must notify the Department in writing in the event of a revocation of patient certification.

Under the statute and the proposed regulations, both practitioners and medical professionals are required to complete a four-hour training course approved by the Department and notify the Department upon completion. An entity that wishes to conduct such a course for continuing education credits to a physician registering to become a practitioner with the Medical Marijuana Program or any medical professional who wishes to be employed by a dispensary may apply online. The online application for approval to provide such a training course can be found here:

<https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/DOH%20-%20Application%20for%20Approval%20to%20Provide%20a%204-hour%20Training%20Course%20in%20the%20Medical%20Marijuana%20Program.pdf>.

### **Dispensaries**

A dispensary applicant would be required to submit an application for a permit and, if awarded a permit, maintain the standards in the proposed regulations to retain the permit received. This requirement has not changed from the temporary regulations. The permit application and required attachments can be found online here:

<https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Dispensaries.aspx>.

In order to apply for a permit, a dispensary would need to have local zoning approval for a dispensary facility; to obtain or construct a facility, including reviewing and approving building plans; to hire and train staff, including developing and revising employment policies and procedures and employment files; to create plans and procedures for the operation of the facility, and to obtain and maintain an electronic tracking system. The dispensary must track the medical marijuana products from the time the dispensary purchases the medical marijuana products from a grower/processor to the dispensing of the medical marijuana products to the patient or caregiver. These requirements are the same as in the temporary regulations.

Under the proposed regulations, the Department would manage the permit application and review process and evaluate dispensary permit applications. This process has not changed from the temporary regulations. The Department would still be required to monitor compliance with the standards to determine that a dispensary should retain a permit, including reviewing complaint and inspection files. The Department has access to and will monitor the electronic tracking system to track medical marijuana products from the dispensaries' purchase of medical marijuana products from the grower/processor through the dispensing to a patient or caregiver in order to prevent diversion of medical marijuana products and to promote public safety. None of these requirements in the proposed regulations has substantially changed from the those in the temporary regulations.

The proposed regulations provide that a dispensary has an obligation to notify the Department: (1) of any complaint made to the dispensary by a patient, caregiver, or practitioner who reports an adverse event from using a medical marijuana product; (2) any delivery vehicle accidents, diversions, losses, or other reportable events that occur during the transportation of medical marijuana products; (3) any unresolved discrepancy in the transport manifest when receiving a delivery of medical marijuana and follow-up report; (4) any complaint made to the dispensary by a patient, caregiver, or practitioner who reports an adverse event from using medical marijuana products dispensed by the dispensary; and (5) that it is applying for approval as a clinical registrant, through the submission of a request to do so.

Further, the proposed regulations provide that a dispensary must maintain: (1) a full and complete plan of operation, to be provided to the Department at the time the Department deems the dispensary operational; (2) a log of any temporarily authorized individuals that enter the facility maintained for four

years and made available upon request to the Department or to State or local law enforcement; (3) an electronic tracking system proscribed by the Department; and (4) transport manifests.

Finally, under the proposed regulations, medical marijuana organizations would be required to comply with local zoning laws. In the event that a new medical marijuana organization were to seek zoning approval from a local government, or to move location, the medical marijuana organization could be required to submit applications and present plans in order to obtain those approvals. This requirement is statutory, reflected in the proposed regulations as it was in the temporary regulations, and has not changed from the time of the implementation of the Program.

### **Growers/Processors**

Under the proposed regulations, a potential grower/processor must submit an application for a permit and maintain standards to retain the permit received. The proposed regulations do not change the requirements found in the temporary regulations. This application and required attachments can be found online here:

<https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Growers-Processors.aspx>.

In order to apply for a permit, the proposed regulations require the grower/processor to have local zoning approval for a grower/processor facility. This is not a change from the temporary regulations, nor from the requirements of the act. In addition, a grower/processor has to obtain or construct a facility, including reviewing and approving building plans; to hire and train staff, including developing and revising employment policies and procedures and employment files; to create plans and procedures for the operation of the facility; and to obtain and maintain a seed-to-sale tracking system with a daily beginning and ending inventory of seeds, immature medical marijuana plants, marijuana plants, medical marijuana, medical marijuana products, and medical marijuana waste. The grower/processor is required to track other information in the system, including tax records, testing and results, point of sale records, including transport manifests, waste disposal records, and recall records. All of these requirements were included in the temporary regulations and are currently being followed by permitted grower/processors.

Under the proposed regulations, the Department would manage the permit application and process and review and evaluate grower/processor applications. This process has not changed from the temporary regulations. The Department would still be required to monitor compliance with the standards to determine that a grower/processor should retain a permit, including review of complaint and inspection files. The Department has access to and will monitor the seed-to-sale electronic tracking system to track medical marijuana from the beginning to the end of the growth, production, and sale process in order to prevent diversion of medical marijuana and to promote public safety. None of these requirements in the proposed regulations has substantially changed from the temporary regulations.

The proposed regulations provide that once a grower/processor is deemed operational, it must provide the Department with a full and complete plan of operation for review. Growers/processors must also maintain: (1) a log of any temporarily authorized individuals that enter its facility for four years, that must be made available upon request to the Department or to State or local law enforcement; (2) an inventory log; (3) a log of all actions taken to detect pests or pathogens, and the measures taken for control; (4) a written process to maintain the sanitation and operation of equipment that comes into contact with medical marijuana; (5) a log recording the maintenance, cleaning, and calibration of equipment; (6) a transport manifest for each delivery vehicle; (7) an electronic tracking system proscribed by the Department, and (8) a record of each application of pesticide, recorded and maintained for four years. These proposed regulations make only minor revisions to the temporary regulations for the sake of clarity and consistency.

Further, the proposed regulations provide that a grower/processor also has a mandatory duty to notify the Department of: (1) any unresolved discrepancy in a transport manifest; (2) its rationale for taking no further action on a reported adverse event caused by medical marijuana or a medical marijuana product; (3) any voluntary recalls of medical marijuana, or medical marijuana products; (4) the discovery of a condition that poses a risk to public health and safety relating to the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products grown or processed at its facility; (5) any delivery vehicle accidents, diversions, losses, or other reportable events that occur during the transportation of medical marijuana products; and (6) that it has applied for approval as a clinical registrant.

The proposed regulations would also require that all permittees submit permit renewal applications annually – the required form is attached as Exhibit A. All permittees would be required to request approval for promotional events and advertising and marketing materials, using Form OMM-003-17 which is attached as Exhibit B. Affiliations with, and un-affiliations from, permittees must be reported using Forms OMM-001-17 and OMM004-17, which are attached as Exhibits C1 and C2, respectively. Dispensaries would be required to submit an application to sell instruments or devices using the required form attached as Exhibit D. Dispensaries would be required submit an application for an additional location if the location was not identified in the initial permit application using the required form attached as Exhibit E. Permittees would also be required to submit a form for approval of alteration of a facility using the required form attached as Exhibit F.

Finally, under the proposed regulations, medical marijuana organizations are required to comply with local zoning laws. In the event that a new medical marijuana organization were to seek zoning approval from a local government, or to move location, the medical marijuana organization could be required to submit applications and present plans in order to obtain those approvals. This requirement is statutory, reflected in proposed regulations as it was in the temporary regulations, and has not changed from the time of implementation of the Program.

### **Laboratories**

The proposed regulations would require that a laboratory submit an application for approval and maintain standards to retain the approval received. The application to become an approved laboratory can be found online here:

<https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Laboratories.aspx>. In order to apply for approval, a laboratory must have an accreditation from an accrediting body whose accreditation is accepted by the Department.

The proposed permanent regulations could require that an existing laboratory renovate its facilities, hire staff, and provide training in order to obtain approval to participate in the Program. To the extent that a new laboratory intends to start up within Pennsylvania to provide this testing, the laboratory may have to obtain local zoning approval for a laboratory. A new laboratory would have to obtain or construct a facility, including reviewing and approving building plans; to hire and train staff, including developing and revising employment policies and procedures and employment files; to create plans and procedures for the operation of the facility; and to purchase equipment.

Under the proposed regulations, in order to participate in the Program, a laboratory must have in place certain policies on reporting to the Department and into the electronic tracking system, so that the Department can review and ensure compliance with the act and regulations. These include: (1) sampling

policies and procedures; (2) a quality assurance program to ensure that its measurements are accurate, errors are controlled, and devices used for testing are routinely and properly calibrated; and (4) copies of four years of the certificates of analysis performed on samples submitted by a grower/processor. These proposed regulations make only minor revisions to the temporary regulations for the sake of clarity and consistency.

Further, the proposed regulations provide that a laboratory must report to the Department: (1) the entry into a written contract with a grower/processor by providing a copy of the contract to the Department; (2) the laboratory's intention to re-test a sample or test another sample from the same harvest batch, harvest lot, or process lot that failed a test; and (3) via written report, the test results of a test sample provided to the laboratory by the Department. These proposed requirements for record keeping and reporting in the proposed regulations make only minor revisions to the temporary regulations for the sake of clarity and consistency.

Finally, a laboratory wishing to participate in the Program, and seeking to build new facilities, could be required to obtain zoning approval from a local government, and to submit applications and to present plans in order to obtain those approvals.

### **Clinical Registrants/Academic Clinical Research Centers**

The proposed regulations require that, in order to be an approved CR, an applicant must file an application for approval with the Department with all pertinent supporting documentation. The application to become a CR can be found online here:

<https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Research.aspx>. This includes an application to be a grower/processor or an application to be a dispensary, if the applicant lacks one or the other permit, or both, if the applicant lacks both permits. A CR must have both a grower/processor permit and a dispensary permit. If a CR applicant already holds a grower/processor permit or a dispensary permit, or both, the CR applicant must also submit a request for conversion of an existing permit to the Department. A CR must renew its approval annually by submitting a renewal application.

The proposed regulations provide that a CR must submit to the Department a written report of the findings of its research program or research study within 365 days of the completion of an approved research program or research study or within 30 days of publication in a peer-reviewed medical journal.

The proposed regulations provide that an accredited medical school must submit an application to the Department to be approved as a certified ACRC. The application to become an academic clinical research center can be found online here:

<https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Research.aspx>.

### **(22a) Are forms required for implementation of the regulation?**

Yes.

**(22b) If forms are required for implementation of the regulation, attach copies of the forms here. If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

Applicable forms are attached. Additional required forms are discussed and the links are provided in the answer to Question 22.

<b>(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.</b>						
	<b>Current FY Year</b>	<b>FY +1 Year</b>	<b>FY +2 Year</b>	<b>FY +3 Year</b>	<b>FY +4 Year</b>	<b>FY +5 Year</b>
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
<b>Regulated Community</b>						
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Savings</b>						
<b>COSTS:</b>						
<b>Regulated Community<sup>1</sup></b>	2,580,000	620,000	620,000	620,000	620,000	620,000
<b>Local Government<sup>2</sup></b>						
<b>State Government</b>						
<b>Total Costs</b>	2,580,000	620,000	620,000	620,000	620,000	620,000
<b>REVENUE LOSSES:</b>						
<b>Regulated Community</b>						
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Revenue Losses</b>						
<b>(23a) Provide the past three year expenditure history for programs affected by the regulation.</b>						
<b>Program</b>	<b>FY -3</b>	<b>FY -2</b>	<b>FY -1</b>	<b>Current FY</b>		
Medical Marijuana Program	3,000,000.	6,988,000.	10,559,000.	9,559,000.		

<sup>1</sup> The Department expects to accept fees from approved CRs. The Department may register up to eight CRs. While there is no cost associated with being approved as a CR or an ACRC, a CR applicant must also obtain or have a permit to be a grower/processor and a dispensary, and there are application fees associated with those permits. A grower/processor is required to pay an initial application fee of \$10,000, an initial permit fee of \$200,000 and a renewal fee of \$10,000. A dispensary is required to pay an initial application fee of \$5,000, an initial permit fee of \$30,000 for each location (up to six per permit) and a renewal fee of \$5,000 that covers all locations. The calculation for the current FY includes only one CR dispensary location. Additional dispensary locations may be added at any time for a fee of \$30,000 for each dispensary location. This current FY calculation also includes permit renewal fees for 25 growers/processors and 50 dispensaries. Following FYs include permit renewal fees for 25 grower/processors and 50 dispensaries as well as the CR permit renewal fees. The calculation for the current FY assumes four additional dispensary locations.

<sup>2</sup> The Department is not able to quantify the additional cost to local governments of potential zoning cases and appeals.

**(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:**

- (a) An identification and estimate of the number of small businesses subject to the regulation.**
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.**
- (c) A statement of probable effect on impacted small businesses.**
- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.**

(a) Due to the fact that the Medical Marijuana Program has only been operating in the Commonwealth since 2017, and that medical marijuana has not been legalized at the federal level, there are no Department of Labor standards and the Department cannot say with certainty whether any dispensary or grower/processor qualifies as a small business. Similar issues arise with respect to the practitioner groups providing certifications and laboratories doing testing. The following information is provided for the purposes of information and not to be taken as a declaration of an entity's status as a small business. The Department will respond to the questions assuming that some, if not all, of the medical marijuana organizations may be considered small businesses.

The proposed permanent regulations apply to dispensaries, which is a type of business that has only legally existed in the Commonwealth since the act's inception. There are currently 56 dispensary permits issued by the Department. The Department does not maintain information on the numbers of employees each dispensary employs. In addition, the federal government does not recognize a dispensary as a legal entity, so information from the federal Department of Labor cannot be utilized to determine which dispensaries are small businesses. Dispensary applications must include information on diversity and each applicant has been scored on diversity.

The proposed permanent regulations apply to growers/processors, which is also a type of business that has only legally existed in the Commonwealth since the act's inception. There are currently 32 grower/processor permits issued by the Department. Again, the Department does not keep information on the number of employed at each grower/processor, and there are no federal requirements that can be applied, because, as with dispensaries, the business activities conducted by growers/processors, while legal in Pennsylvania, are not recognized as legal by the federal government. Like dispensaries, grower/processor applications must include information on diversity, and each applicant has been scored on diversity.

The proposed permanent regulations apply to laboratories approved by the Department to test medical marijuana and medical marijuana products by the Department. There are currently seven approved laboratories in the Commonwealth.

The proposed permanent regulations also apply to seven CRs, each of which holds a grower/processor permit and a dispensary permit. Those types of entities are discussed above. The proposed regulations also apply to certified ACRCs, which are educational institutions with medical schools. There are currently eight CRs and eight certified ACRCs in the Commonwealth. The Department may approve no more than eight CRs under the act.

(b) The proposed regulations make little change to the reporting, recordkeeping and other administrative requirements for the operation of the Program that are in the temporary regulations:

### **Dispensaries**

The proposed regulations require, as do the temporary regulations, that a dispensary apply for and obtain a permit from the Department. A dispensary would be required to hire and train staff, including developing and revising employment policies and procedures and employment files, and create plans and procedures for the operation of the facility. A dispensary would be required to maintain and update an electronic tracking system for sales and dispensing of medical marijuana products. The dispensary must track the medical marijuana products from the time the dispensary purchases the medical marijuana products from a grower/processor to the dispensing of the medical marijuana products to the patient or caregiver.

Costs relating to these requirements are addressed in the response to Question 19.

### **Grower/Processors**

The proposed regulations require, as do the temporary regulations, that growers/processors apply for and obtain a permit from the Department. A grower/processor would be required to hire and train staff, including developing and revising employment policies and procedures and employment files, and to create plans and procedures for the operation of the facility. A grower/processor would be required as part of its plans and procedures for operation to take medical marijuana waste disposal into account.

A grower/processor would be required to enter information regarding a daily beginning and ending inventory of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, medical marijuana products, and medical marijuana waste into the electronic seed-to-sale tracking system. The grower/processor must also track other information in the system, including tax records, testing and results, and point-of-sale records, including transport manifests, medical marijuana disposal records, and recall records. A grower/processor would be required by law and regulation to educate its employees and principals on how to report information in the electronic seed-to-sale system.

Costs related to these requirements are addressed in the response to Question 19.

### **Laboratories**

The proposed regulations require laboratories to apply for and obtain approval from the Department, as do the temporary regulations. A laboratory seeking Department approval would not be charged a fee for the application for laboratory approval but would be required to secure accreditation for medical marijuana testing from an accrediting body accepted by the Department. Accrediting bodies do charge a fee to a laboratory for obtaining and maintaining accreditation. These costs include maintaining the equipment to certain calibration standards, and auditing results. The Department expects that some of these costs will be offset through fees charged to growers/processors by laboratories for the testing required under the act.

The proposed regulations would require a laboratory to hire and train staff, including developing and revising employment policies and procedures and employment files, and create plans and procedures for the operation of the facility and purchasing equipment and training staff.

### **Clinical Registrants/Academic Clinical Research Centers**

Under the proposed regulations, in order to be an approved CR, an applicant must file an application for approval with the Department. A CR applicant must apply for, or hold, a grower/processor permit and a

dispensary permit. If a CR applicant already holds a grower/processor permit or a dispensary permit, or both, the CR applicant must also submit a request for conversion of an existing permit to the Department. A CR must renew its approval annually by submitting a renewal application. An accredited medical school must submit an application to the Department to be approved as a certified ACRC. Fees are listed in the Department's response to Question 19.

(c) The Department does not anticipate any impact to small businesses other than that already addressed in discussions of the impact on the regulated community.

(d) No alternative method to achieving the purpose of the proposed regulations was considered, as the statute requires that the Department to first issue temporary regulations necessary to achieve the act's purpose within a particular time frame, that those temporary regulations expire within two years of publication in the *Pennsylvania Bulletin*, and that all future regulations would be required to be promulgated through the regulatory process set out in law. Regulations are necessary for compliance with, and enforcement of, the act, as is discussed in the response to Question 10.

**(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.**

The proposed regulations include provisions to allow for patients who may have mobility issues, or who, for some other reason, cannot obtain an ID card, to be issued a medical marijuana patient authorization letter. The Department has also reiterated in the proposed regulations the statutory requirements allowing for if an applicant demonstrates financial hardship. Beyond that, the Department has not developed any other special provisions.

**(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.**

No other alternative provisions were considered.

**(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:**

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Due to the fact that the Medical Marijuana Program has only been operating in the Commonwealth since 2017, and the fact that medical marijuana has not been legalized at the federal level, so that no

Department of Labor standards apply to medical marijuana organizations, the Department cannot say with certainty whether any dispensary, grower/processor, or lab qualifies as a small business. Whether or not any of these regulated entities are small businesses, however, the Department has not and would not consider less stringent requirements than those offered in this proposed rulemaking. The Department's need for strict oversight is driven by its responsibility to ensure the safety, security, and effectiveness of the Program.

**(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.**

No data has been considered.

**(29) Include a schedule for review of the regulation including:**

- A. The length of the public comment period:** \_\_\_\_\_
- B. The date or dates on which any public meetings or hearings will be held:** \_\_\_\_\_
- C. The expected date of delivery of the final-form regulation:** \_\_\_\_\_
- D. The expected effective date of the final-form regulation:** \_\_\_\_\_
- E. The expected date by which compliance with the final-form regulation will be required:** \_\_\_\_\_
- F. The expected date by which required permits, licenses or other approvals must be obtained:** \_\_\_\_\_

A. The agency will accept public comment for 30 days after publication of the proposed rulemaking in the *Pennsylvania Bulletin*.

B. Given that stakeholders had input on the temporary regulations, and these proposed regulations are substantially similar, there are no expected public meetings or hearings.

C. The Department expects to publish the final-form rulemaking in sufficient time for the final-form rulemaking to become effective prior to the expiration of the current temporary regulations.

D. The Department expects that the final-form rulemaking will be effective on the date of publication.

E. Compliance will be required on the date of publication of the final-form rulemaking.

F. No deadlines are required for permits, licenses, or other approvals.

**(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.**

The Department continually reviews the validity and efficacy of its regulations and will do so with these regulations as well.



**OFFICE OF MEDICAL MARIJUANA  
PERMIT RENEWAL APPLICATION  
(28 Pa. Code § 1141.36)**

**Generally**

A medical marijuana organization wishing to renew its permit shall submit a permit renewal application with the applicable fee to the Department not more than 6 months, nor less than 4 months, prior to the current permit's expiration.

A medical marijuana organization shall include the following in the permit renewal application:

(1) Information regarding any charge, or any initiated, pending or concluded investigation, during the period of the initial permit or prior renewal period, by any governmental or administrative agency with respect to:

(i) Any incident involving the theft, loss or possible diversion of medical marijuana by the medical marijuana organization or from the medical marijuana organization's facility.

(ii) Compliance by the medical marijuana organization with the laws of the Commonwealth with respect to any substance in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).

(2) Information concerning the medical marijuana organization's ability to carry on the activity for which the permit was issued, including medical marijuana product shortages or wait lists occurring during the 12 months prior to the date the renewal permit application was submitted.

(3) The medical marijuana organization's history of compliance with the act and the temporary regulations.

If the Department determines that a permit renewal application is complete but lacking sufficient information upon which to make a determination, the Department will notify the medical marijuana organization in writing of the factors that require additional information and documentation. The medical marijuana organization shall have 30 days from the mailing date of the notice to provide the requested information and documentation to the Department. A medical marijuana organization's failure to provide the requested information to the Department by the deadline may be grounds for denial of the permit renewal application.

**Fees**

The permit renewal fee must be submitted with the Permit Renewal Application in the form of a certified check or money order made payable to "Commonwealth of Pennsylvania." The permit renewal fee must be enclosed in a separate envelope within the permit renewal application package. The permit renewal fee for the Permit Renewal Application is refundable if the renewal permit is not granted.

The following fees must be submitted with the permit renewal application.

Permit Renewal Fee for a grower/processor permit.....	\$ 10,000
Permit Renewal Fee for a dispensary permit.....	\$ 5,000



**OFFICE OF MEDICAL MARIJUANA  
PERMIT RENEWAL APPLICATION  
(28 Pa. Code § 1141.36)**

**Submission of Permit Renewal Application**

All sections of the Permit Renewal Application must be completed. All sections must be saved as a PDF file on a single USB drive in accordance with the following file naming format: (name on permit]-*Permit Renewal Application.pdf*.

Please make sure the permit renewal application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

Send the permit renewal application package, along with the required fee, to the following address:

Office of Medical Marijuana  
Permit Renewal Application  
Department of Health  
Room 628, Health and Welfare Building  
625 Forster Street  
Harrisburg, PA 17120



**OFFICE OF MEDICAL MARIJUANA  
PERMIT RENEWAL APPLICATION  
(28 Pa. Code § 1141.36)**

<b>Medical Marijuana Organization (MMO)</b>		
Name of MMO:	Submission Date:	
Primary Contact:	Permit Number:	
Phone Number:	Email Address:	
<b>Existing Facility Information</b>		
Check the type of facility.		
<input type="checkbox"/> Grower/processor	<input type="checkbox"/> Dispensary	
Provide the existing facility's name and primary address.		
Name of Facility:		
Street Address:		
City, Zip Code:		
Municipality and County:		
If the applicant is a dispensary, provide the facility's second location name and address, if applicable.		
Name of Facility:		
Street Address:		
City, Zip Code:		
Municipality and County:		
If the applicant is a dispensary, provide the facility's third location name and address, if applicable.		
Name of Facility:		
Street Address:		
City, Zip Code:		
Municipality and County:		
<b>Documentation</b>		
The medical marijuana organization should check off each of the requirements below and attach the applicable documentation with the Permit Renewal Application.		
<input type="checkbox"/>	A copy of the letter from the Department approving the initial application and granting the permit.	
<input type="checkbox"/>	A copy of the initial application filed with the Department for the permit with additional information provided for the following sections:	
<input type="checkbox"/>	Part A, Section 1. Applicant Name, Address and Contact Information	Provide any changes to the applicant's name, address and contact information since the initial permit application was submitted to the Department.
<input type="checkbox"/>	Part B, Diversity Plan	Attach a current diversity plan for each location covering diversity activities carried out in the previous permit year.
<input type="checkbox"/>	Part C, Section 4. Principals, Financial Backers, Operators, and Employees.	Attach a list of any principals, financial backers, operators, and employees that have been added to the medical marijuana organization since the issuance of the initial permit by the Department.

**OFFICE OF MEDICAL MARIJUANA  
PERMIT RENEWAL APPLICATION  
(28 Pa. Code § 1141.36)**

<b>Documentation</b>		
The medical marijuana organization should check off each of the requirements below and attach the applicable documentation with the Permit Renewal Application.		
<input type="checkbox"/>	Part D, Section 8. Operational timetable.	Attach a timetable for each permitted location that outlines the steps that will be taken during the renewed permit period for each permitted location to become operational or to complete any additional construction phases to the permitted location.
<input type="checkbox"/>	Part F, Section 23. Community Impact	Attach a current community impact statement for each permitted location covering community activities that the medical marijuana organization was involved in for the previous permit year.
<input type="checkbox"/>	Part D, Section 10. Security and Surveillance	Attach a statement outlining the security and surveillance methods and procedures that are in place at each permitted location.
<input type="checkbox"/>	Part D, Section 16. Sanitation and Safety	Attach a statement of the intended sanitation and safety measures that are in place at each permitted location.
<input type="checkbox"/>	Attachment D: Site and Facility Plan	Attach copies of the site plan for each permitted location. Copies should include any additional construction phases that will be completed during the renewed permit period. Include any documentation provided by the local municipality that shows compliance with local zoning requirements.
<input type="checkbox"/>	A copy of the insurance declaration page that lists insurance coverage limits for each permitted location that will be covered during the permit renewal period.	
<input type="checkbox"/>	A statement concerning the medical marijuana organization's ability to carry on the activity for which the permit was issued. The statement should include information concerning shortages of medical marijuana product or wait lists relevant to the medical marijuana organization's operation that occurred during the 12 months prior to the date the renewal permit application was submitted.	
<input type="checkbox"/>	Any information, if applicable, regarding any charge, or any initiated, pending or concluded investigation, during the period of the initial permit by any governmental or administrative agency with respect to:	
<input type="checkbox"/>	Any incident involving the theft, loss or possible diversion of medical marijuana by the medical marijuana organization or from the medical marijuana organization's facility.	
<input type="checkbox"/>	Compliance by the medical marijuana organization with the laws of the Commonwealth with respect to any substance in section 4 of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-104).	

**OFFICE OF MEDICAL MARIJUANA  
PERMIT RENEWAL APPLICATION  
(28 Pa. Code § 1141.36)**

**Documentation**

The medical marijuana organization should check off each of the requirements below and attach the applicable documentation with the Permit Renewal Application.

- |                          |  |
|--------------------------|--|
| <input type="checkbox"/> | A statement of the medical marijuana organization's history in complying with the act, including a summary that explains how the medical marijuana organization implemented all of its standard operating procedures that were approved by the Department. |
| <input type="checkbox"/> | A signed statement that all other sections of the initial permit application remain unchanged and will apply to each permitted location during the permit renewal period.  |

**Attestation**

I acknowledge that a false statement made by me in this Permit Renewal Application is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

Signature	Date
Printed Name	Title in MMO

**Questions about this form can be submitted to: [tbosack@pa.gov](mailto:tbosack@pa.gov).**

# OFFICE OF MEDICAL MARIJUANA

## REQUEST FOR APPROVAL PROMOTIONAL, ADVERTISING AND MARKETING MATERIALS

Pursuant to regulation § 1141.50 (relating to advertising by a medical marijuana organization) promotional, advertising and marketing materials shall be approved by the Department prior to their use.

This form must be submitted to the Office of Medical Marijuana by a medical marijuana organization before any materials, prepared by or on behalf of the medical marijuana organization, may be used to promote, advertise or market the name of the medical marijuana organization or the promotion, advertising and marketing of any portion of the Medical Marijuana Program.

All sections of the request form must be completed. The request form should be submitted electronically to DH, PressOffice < [RA-DHPRESSOFFICE@pa.gov](mailto:RA-DHPRESSOFFICE@pa.gov) >

Medical Marijuana Organization (MMO)	
Name of MMO:	Submission Date:
Primary Contact:	
Phone Number:	Email Address:
List of Promotional, Advertising or Marketing Material	
Please check the MMO type that is making the request.	
<input type="checkbox"/> Grower/processor <input type="checkbox"/> Dispensary <input type="checkbox"/> Both	
Please attach a pdf file showing all materials that the MMO is requesting to be approved by the Office of Medical Marijuana.	
Please describe the event or events that the MMO will be using the attached materials.	
Please describe the audience that will be receiving the promotional, advertising or marketing materials.	
Office of Medical Marijuana – Form OMM003-17	

**Attestation**

I acknowledge that none of the materials attached to this form will be used by the Medical Marijuana Organization to provide to patients, caregivers, practitioners, medical professionals or any member of the general public, either free or for sale, at the facility or site of the medical marijuana organization.

I acknowledge that a false statement made by me in this document is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Title in MMO

**Submit this form with required attachments to:** [RA-DHPRESSOFFICE@pa.gov](mailto:RA-DHPRESSOFFICE@pa.gov)

**Office of Medical Marijuana – Form OMM003-17**

**Regulation Section**

**§ 1141.50. Advertising by a medical marijuana organization.**

(a) In the advertising and marketing of medical marijuana, a medical marijuana organization shall be consistent with the Federal regulations governing prescription drug advertising and marketing in 21 CFR 202.1 (relating to prescription-drug advertisements).

(b) Promotional, advertising and marketing materials shall be approved by the Department prior to their use.

(c) This part does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana items that the grower/processor is offering for sale to the dispensary.

**OFFICE OF MEDICAL MARIJUANA**  
**REPORTING INDIVIDUALS AFFIIATED**  
**WITH A MEDICAL MARIJUANA ORGANIZATION**

**Note: This form must be submitted by a medical marijuana organization for each financial backer, principal, operator and employee listed in the initial permit application and for each financial backer, principal, operator and employee added by the organization after the submission of the initial permit application. A medical marijuana organization shall submit this form and any other required documentation electronically to the Department, at the address below, after each financial backer, principal, operator and employee submits fingerprints for an FBI criminal background check. To complete the FBI criminal background check process, each principal, financial backer, operator and employee shall submit by mail to the Department, the original FBI criminal history report received from the Pennsylvania State Police.**

Medical Marijuana Organization (MMO)	
Name of MMO:	Submission Date:
Permit Number:	Region:
Primary Contact:	Phone Number:
Classification Information	
The individual listed in this form is one of the following (check all the following that apply):	
<input type="checkbox"/> Financial Backer <input type="checkbox"/> Principal <input type="checkbox"/> Operator <input type="checkbox"/> Employee	
Individual's Information	
Name:	
Mailing Address:	Email address:
	Telephone Number:
	Cell Phone Number:
Attestation	
<p>I acknowledge that I am not using this form to effectuate the transfer or sale of a medical marijuana permit from the entity to which the permit was initially issued, as permits are nontransferable pursuant to 35 P.S. § 10231.603(b). I further acknowledge that a false statement made by me in this document is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).</p>	
Signature	Date
Printed Name	Title in MMO
<b>Submit this form with required attachments to: <a href="mailto:tbosack@pa.gov">tbosack@pa.gov</a></b>	
<b>Mail the Original Criminal History Record Report to:</b> <b>The PA Department of Health</b> <b>Attn: Field Operations</b> <b>Health and Welfare Building, Room 628</b> <b>625 Forster Street</b> <b>Harrisburg, PA 17102</b>	

**OFFICE OF MEDICAL MARIJUANA**  
**REPORTING INDIVIDUALS NO LONGER AFFILIATED**  
**WITH A MEDICAL MARIJUANA ORGANIZATION**

**Note: This form must be submitted by a medical marijuana organization for each financial backer, principal, operator and employee listed in the initial permit application and for each financial backer, principal, operator and employee who is no longer affiliated with the medical marijuana organization. A medical marijuana organization shall submit this form electronically to the Office of Medical Marijuana.**

<b>Medical Marijuana Organization (MMO)</b>	
Name of MMO:	Submission Date:
Permit Number:	Region:
Primary Contact:	Phone Number:
<b>Classification Information</b>	
The individual listed in this form is one of the following (check all the following that apply):	
<input type="checkbox"/> Financial Backer <input type="checkbox"/> Principal <input type="checkbox"/> Operator <input type="checkbox"/> Employee	
<b>Individual's Information</b>	
Name:	
Mailing Address:	Email address:
	Telephone Number:
	Cell Phone Number:
Job Title:	
Date Individual Left Organization:	
<b>Attestation</b>	
<p>I acknowledge that I am not using this form to effectuate the transfer or sale of a medical marijuana permit from the entity to which the permit was initially issued, as permits are nontransferable pursuant to 35 P.S. § 10231.603(b). I further acknowledge a false statement made by me in this document is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).</p>	
_____ Signature	_____ Date
_____ Printed Name	_____ Title in MMO
<b>Submit this document electronically to : <a href="mailto:tabosack@pa.gov">tabosack@pa.gov</a></b>	

**Office of Medical Marijuana – Form OMM004-17**

**OFFICE OF MEDICAL MARIJUANA  
APPLICATION FOR SALE OF INSTRUMENTS  
OR DEVICES IN A DISPENSARY  
(28 Pa. Code §1161.27)**

A dispensary may sell, offer for sale or provide at a facility, with the prior written approval of the Department, instruments, devices and services related to the use of medical marijuana products. 28 Pa. Code § 1161.27(c). A dispensary may only sell those instruments, devices and services related to the use of medical marijuana products that are marked as approved by the Department in the application. A dispensary shall submit this application listing all products it intends to purchase and any other documentation that may be required electronically to the Department. A dispensary must also provide its PA sales tax number. If a dispensary does not have a PA sales tax number, please contact the Office of Medical Marijuana for more information.

**Instruments or devices related to the use of medical marijuana products**

<b>Section 1. Dispensary Information</b>	
Medical Marijuana Organization:	Permit No.:
	PA Sales Tax Number:
MMO Address:	
Dispensary name and address that will be offering the products:	
Dispensary name and address that will be offering the products:	
Dispensary name and address that will be offering the products:	
Person Completing Form:	
Phone Number:	

<b>Section 2. Seller Information</b>
Name of the company offering to sell an instrument or device to the dispensary:
Company Address:
Company phone number:
Company website:
Company OTP (Other Tobacco Permit) number. (A dispensary may only purchase vaporization pens from a company that has an “Other Tobacco Permit” issued by the PA Department of Revenue.)

**OFFICE OF MEDICAL MARIJUANA  
APPLICATION FOR SALE OF INSTRUMENTS  
OR DEVICES IN A DISPENSARY  
(28 Pa. Code §1161.27)**

<b>Product Information</b>
Name of instrument or device (include serial number if available):
Product Description (include the intended use of the product by a patient):
Website information (please provide a link to the product on the company's website or another website showing the product if no company website is available.)

<b>Attestation</b>	
I acknowledge that instruments or devices approved by the Department in this application will be offered for sale by the medical marijuana organization only at the facility or facilities listed in this application and only to a patient or caregiver with a valid ID card issued by the Office of Medical Marijuana.	
I acknowledge that a false statement made by me in this document is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).	
_____ Signature	_____ Date
_____ Printed Name	_____ Title in MMO
<b>Submit this form with required attachments to: <a href="mailto:tbosack@pa.gov">tbosack@pa.gov</a>.</b>	

**OFFICE OF MEDICAL MARIJUANA  
APPLICATION FOR SALE OF INSTRUMENTS  
OR DEVICES IN A DISPENSARY  
(28 Pa. Code §1161.27)**

**Attachment: Additional Instruments or Devices**

Attach this page to the application for each additional instrument or device being requested to be approved by the Department.

<b>Section 2. Seller Information</b>
Name of the company selling an instrument or device to the dispensary:
Company address:
Company phone number:
Company website:
Company OTP (Other Tobacco Permit) number. (A dispensary shall only purchase vaporization pens from a company that has an "Other Tobacco Permit" issued by the PA Department of Revenue.)
<b>Product Information</b>
Name of Product (include serial number if available):
Product Description (include the intended use of the product by a patient):
Website information (please provide a link to the product on the company's website or another website if the no company website is available.)



**OFFICE OF MEDICAL MARIJUANA  
APPLICATION FOR ADDITIONAL DISPENSARY LOCATION  
(28 Pa. Code §1161.40)**

A dispensary permit shall include a primary dispensary facility location, and up to two additional dispensary facility locations. A permittee may file an application § 1161.40 (Application for additional dispensary locations) for an additional dispensary facility location to be added to the initial permit.

A dispensary may not begin operations at an additional location until the Department approves the application for additional dispensary location.

**Fees**

The Application and Permit Fee must be submitted with the Application for Additional Dispensary Location in the form of certified check or money order made out to “Commonwealth of Pennsylvania.” Both fees must be enclosed in a separate envelope within the application package. The application fee for the Application for Additional Dispensary Location is non-refundable. The permit fee will be refunded if the Application for Additional Dispensary Location is not approved.

The following fee must be submitted with the application.

Application for Additional Dispensary Locations.....	\$ 5,000
A permit fee for the dispensary location.....	\$ 30,000

**Submission**

The medical marijuana organization must submit a separate Application for Additional Dispensary Locations for each additional dispensary facility.

All sections of the Application for Additional Dispensary Locations must be completed. The application must be saved as a PDF files on a single USB drive in accordance with the following file naming format: *AdditionalDispensaryLocation.pdf*.

Please make sure the application is properly signed and dated. A signature may be scanned and provided electronically in a pdf file.

Send the application package, along with the required fee, to the following address:

Office of Medical Marijuana  
Additional Dispensary Location Application  
Department of Health  
Room 628, Health and Welfare Building  
625 Forster Street  
Harrisburg, PA 17120



**OFFICE OF MEDICAL MARIJUANA  
APPLICATION FOR ADDITIONAL DISPENSARY LOCATION  
(28 Pa. Code §1161.40)**

<b>Medical Marijuana Organization (MMO)</b>	
Name of MMO:	Submission Date:
Primary Contact:	Permit Number:
Phone Number:	Email Address:
<b>Proposed Facility Information</b>	
Name of Proposed Facility:	
Street Address:	
City, Zip Code:	
Municipality and County:	
<b>Documentation</b>	
The medical marijuana organization should check off each of the statements below and attach the applicable documentation.	
<input type="checkbox"/>	A copy of the initial application filed with the Department for the permit with information provided for the following sections:
<input type="checkbox"/>	Section 1. Applicant Name, Address and Contact Information
<input type="checkbox"/>	Section 2. Dispensary Information.
<input type="checkbox"/>	Part C, Section 4. Principals, Financial Backers, Operators, and Employees.
<input type="checkbox"/>	Part D, Section 8. Operational timetable.
<input type="checkbox"/>	Part D, Section 10. Security and Surveillance
<input type="checkbox"/>	Part D, Section 16. Sanitation and Safety
<input type="checkbox"/>	Part F, Section 23. Community Impact
	Provide any changes to the applicant’s name, address and contact information since the initial application for a permit was filed with the Department.
	Indicate the existing facility location authorized by the permit and provide a general statement about the proposed location.
	Attach a list of any principals, financial backers, operators, and employees that have been added to medical marijuana organization since the issuance of the permit by the Department.
	Attach a timetable for the proposed location indicating the steps that will be taken for the proposed location to become operational within 6-months from the date the proposed location is approved by the Department.
	Attach a statement outlining the security and surveillance methods and procedures that will be implemented at the proposed location.
	Attach a statement of the intended sanitation and safety measures that will be implemented at the proposed location.
	Attach a statement describing the positive impact the proposed location will have on the community and patients.



**OFFICE OF MEDICAL MARIJUANA  
APPLICATION FOR ADDITIONAL DISPENSARY LOCATION  
(28 Pa. Code §1161.40)**

<b>Documentation</b>		
The medical marijuana organization should check off each of the statements below and attach the applicable documentation.		
<input type="checkbox"/>	Attachment C: Property Title, Lease, or Option to Acquire Property Location	Attach copies of any documentation for the proposed location showing an ownership interest in the proposed location.
<input type="checkbox"/>	Attachment D: Site and Facility Plan	Based on the instructions, attach copies of the site plan for the proposed location. Include any documentation provided by the local municipality showing the dispensary location complies with local zoning requirements and can operate at the proposed location as a dispensary.
<input type="checkbox"/>	A signed statement that all other sections of the initial application remain unchanged and will apply to the proposed dispensary location.	
<input type="checkbox"/>	A signed statement that the applicant has performed a search of available public records and the proposed dispensary location is not within 1,000 feet of the property line of a public, private or parochial school or a day-care center.	
<b>Attestation</b>		
I acknowledge that a false statement made by me in this document is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation).		
_____ Signature	_____ Date	
_____ Printed Name	_____ Title in MMO	
<b>Questions about this form can be submitted to:</b> <a href="mailto:tbosack@pa.gov" style="color: blue;">tbosack@pa.gov</a> .		

**Office of Medical Marijuana – Form OMM0010-17**

**Office of Medical Marijuana  
Application for Approval of Alteration of a Facility  
28 Pa. Code § 1141.41**

<b>Facility Information</b>		
<b>Permit Number</b>	<b>Primary Contact</b>	<b>Proposed Location</b>
		Name: Street Address: City, Zip Code: Municipality/County:

<b>28 Pa. Code § 1141.41 requirements</b>	
(a) Except as provided in subsection (b), after the issuance of a permit, a medical marijuana organization may not make a physical change, alteration or modification to the facility that materially or substantially alters the facility or its usage as listed in the plot plans originally approved by the Department.  (b) A medical marijuana organization wishing to make any of the following alterations to the facility for which its permit was issued shall submit an application for approval of alteration of a facility, on a form prescribed by the Department, to the Department together with the fee required under § 1141.28 (relating to fees):	
Mark all that apply to this application:	
(1) An increase or decrease in the total square footage of the facility. <input type="checkbox"/> YES <input type="checkbox"/> NO  (2) The sealing off, creation of or relocation of a common entryway, doorway, passage or other means of public ingress or egress when the common entryway, doorway or passage alters or changes limited access areas. <input type="checkbox"/> YES <input type="checkbox"/> NO  (3) Any of the following made to enhance activities authorized under the permit:	
(i) Additional electric fixtures or lighting equipment. <input type="checkbox"/> YES <input type="checkbox"/> NO	
(ii) The lowering of a ceiling. <input type="checkbox"/> YES <input type="checkbox"/> NO	
(iii) Electrical modifications that require inspection by the local municipality. <input type="checkbox"/> YES <input type="checkbox"/> NO	

**Office of Medical Marijuana  
Application for Approval of Alteration of a Facility  
28 Pa. Code § 1141.41**

<b>Documentation to be Submitted</b>		
<b>Document</b>	<b>Initial Application Updates</b>	<b>Submitted</b>
Initial Application	A copy of the initial application filed with the Department for the permit with information provided for the following sections.	
Initial Application	Section 1. Applicant Name, Address and Contact Information.	
	Section 2. Facility Information.	
	Part C, Section 4. Principals, Financial Backers, Operators, and Employees.	
	Attached a list of affiliates added since initial application was approved.	
	Background check process has been completed for all affiliates listed as part of the medical marijuana organization.  <b>Completed by compliance officer. An MMO affiliation form has been received for each principals, financial backers, operators, and employees and background checks information has been reviewed.</b>	
	Part D, Section 8. Operational Timetable.	
	Attached a timetable for the proposed alteration(s).	
	Part D, Section 10. Security and Surveillance	
	Attached a statement of any additions to the security and surveillance plan that will be necessary as a result of the facility alteration(s).	
		Part D, Section 16. Sanitation and Safety.
Attached a statement of the intended sanitation and safety measures that will be implemented at the altered location.		

**Office of Medical Marijuana  
Application for Approval of Alteration of a Facility  
28 Pa. Code § 1141.41**

	Part F, Section 23. Community Impact	
	Attached a statement describing the positive impact the proposed alteration will have on the community and/or patients.	
	Attachment D: Site and Facility Plan	
	Attached site plan and zoning documentation for the altered location.	
Permittee Statement	A signed statement that all other sections of the initial application are unchanged and apply to the altered location.	
Other forms	As required.	
Payment	Required payment was enclosed with the application.	

**Office of Medical Marijuana  
Application for Approval of Alteration of a Facility  
28 Pa. Code § 1141.41**

<b>Dispensary Information</b>		
Permit Number	Primary Contact	Proposed Location
		Name: Street Address: City, Zip Code: Municipality/County:

**RECOMMENDATION**

All documentation required in the Application for Approval of Alteration of a Facility has been submitted by \_\_\_\_\_, the primary contact for \_\_\_\_\_,  YES  NO

Field Operations recommends the Approval of Alteration of a Facility submitted by \_\_\_\_\_, LLC.  YES  NO

Assistant Director and Chief Compliance Officer	Date

**APPROVED**

The Approval of Alteration of a Facility has been reviewed by Director for the Office of Medical Marijuana.  YES  NO

The Approval of Alteration of a Facility submitted by \_\_\_\_\_, is approved.  YES  NO

Director, Office of Medical Marijuana	Date