RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH [28 PA. CODE CH. 1191]

Medical Marijuana; Patients and Caregivers; Temporary Regulations

The Department of Health (Department) is publishing temporary regulations in Chapter 1191 (relating to patients and caregivers) to read as set forth in Annex A. The temporary regulations are published under the Medical Marijuana Act (act) (35 P.S. §§ 10231.101—10231.2110). Section 1107 of the act (35 P.S. § 10231.1107) specifically provides that, to facilitate the prompt implementation of the act, the Department may promulgate temporary regulations that are not subject to sections 201—205 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201—1205), known as the Commonwealth Documents Law, the Regulatory Review Act (71 P.S. §§ 745.1—745.14) and sections 204(b) and 301(10) of the Commonwealth Attorneys Act (71 P.S. §§ 732-204(b) and 732-301(10)).

To implement the Medical Marijuana Program, the Department will be periodically publishing temporary regulations regarding various sections of the act. The temporary regulations for patients and caregivers will expire on November 12, 2019.

Chapter 1191 pertains to patients and caregivers who wish to participate in the Medical Marijuana Program, including requirements for identification cards, application fees, background checks for caregivers, and the patient and caregiver registry. The next set of temporary regulations that the Department anticipates publishing relate to academic clinical research centers.

Interested persons are invited to submit written comments, suggestions or objections regarding the temporary regulations to John J. Collins, Office of Medical Marijuana, Department of Health, Room 628, Health and Welfare Building, 625 Forster Street, Harrisburg, PA 17120, (717) 787-4366, RA-DHMedMarijuana@pa.gov. Persons with a disability who wish to submit comments, suggestions or objections regarding the temporary regulations may do so by using the previous contact information. Speech and/or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT). Persons who require an alternative format of this document may contact John J. Collins so that necessary arrangements may be made.

RACHEL L. LEVINE, MD, Acting Secretary

(Editor's Note: Title 28 of the Pennsylvania Code is amended by adding temporary regulations in §§ 1191.21—1191.33 to read as set forth in Annex A.)

Fiscal Note: 10-205. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

CHAPTER 1191. PATIENTS AND CAREGIVERS

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§ 1191.21. Definitions.

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

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

Applicant—

- (i) A patient or a caregiver who submits an identification card application to the Department.
- (ii) The term includes a legal guardian or a parent who submits an application on behalf of a patient.
- (iii) 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.

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 of section 506(2) of the act $(35 \text{ P.S.} \S 10231.506(2))$.

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.

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

Medical marijuana patient authorization letter—A document issued by the Department under § 1191.32 (relating to medical marijuana patient authorization letters).

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

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

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 § 1181.27 (relating to issuing patient certifications) certifying that a patient has one or more serious medical conditions.

Pennsylvania Justice Network—An integrated justice portal that provides a common online environment for authorized users to access public safety and criminal justice information.

§ 1191.22. 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), including all of 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 § 1191.27 (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.

§ 1191.23. 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 § 1191.32 (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, as determined by the Department, is made to the Department that the individual should be permitted to serve as a caregiver.
- (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.

§ 1191.24. 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 withdraw of a patient certification by a practitioner under § 1181.29 (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 to the patient.
- (b) A medical marijuana cardholder shall return the identification card to the Department within 10 business days following receipt of written notice from the Department of the occurrence of any of the following:
- (1) The removal of the medical marijuana cardholder from the patient and caregiver registry under § 1191.30 (relating to revocation or suspension of identification card; removal or suspension from the patient and caregiver registry).
- (2) The Department has received notification from the practitioner who issued the patient certification to the patient of the occurrence of any of the circumstances described in § 1181.29(b).

§ 1191.25. Application for, and issuance 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, all of the following:
- (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 will be provided by the practitioner to the Department under § 1181.27(c)(2) (relating to issuing patient certifications).
- (6) The appropriate fee or proof of financial hardship as provided for in § 1191.26 (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, all of 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 is not authorized to serve as a caregiver unless and until the individual submits an application under subsection (d) and is issued an identification card by the Department.
- (d) An identification card application submitted by a caregiver must include, at a minimum, all of the following:
- (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 § 1181.27(c)(2).
- (5) A copy of the criminal history record information required under § 1191.27 (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 § 1191.26.
 - (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 § 1191.27 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 5 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.

§ 1191.26. Application fees.

- (a) An applicant shall submit a fee of \$50 with an identification card application or identification card renewal application.
- (b) Notwithstanding subsection (a), an applicant shall submit a fee of \$25 under the following circumstances:
- (1) The Department issues a replacement identification card as a result of a lost, stolen, destroyed, defaced or illegible identification card.
- (2) The patient's practitioner has been removed from the practitioner registry under § 1181.26 (relating to removal of a practitioner from the practitioner registry) and the patient applies for a new identification card.
- (c) The Department may establish higher fees for issuance of a second and subsequent replacement identification cards. Each January, the Department will post on its publicly-accessible web site the fees for issuance of a second and subsequent replacement identification cards, and will publish notice of those fees in the *Pennsylvania Bulletin*.
- (d) Subject to § 1191.32 (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. Each January, 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*.

§ 1191.27. 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 its authorized agent for the purpose of obtaining a criminal history record check. The Pennsylvania State Police or its authorized agent will submit the fingerprints to the Federal Bureau of Investi-

gation 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.

§ 1191.28. 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 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 1 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 1 year from the date of issuance.
- (2) Any of the events listed under subsection (d)(2) or (3).
 - (3) The date the caregiver dies.
- (f) A medical marijuana cardholder shall apply to the Department for a replacement identification card within 10 business days of discovering the loss or defacement of the identification card.

§ 1191.29. 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. A medical marijuana cardholder shall include with the identification card renewal application a new or updated patient certification issued by the patient's practitioner, which will be provided by the practitioner to the Department under § 1181.27(c)(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.

§ 1191.30. Revocation or suspension of identification card; removal or suspension from the patient and caregiver registry.

- (a) The Department may revoke or suspend a medical marijuana cardholder's identification card and remove the patient or caregiver from the patient and caregiver registry upon the occurrence of any of the following:
- (1) The Department receives written notice from a practitioner under § 1181.29(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) Information obtained from the Pennsylvania Justice Network indicates that a caregiver has been convicted of a criminal offense relating to the sale or possession of drugs, narcotics or controlled substances after being issued an identification card.
- (4) 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.
- (5) 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.
- (6) 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 has been removed from the practitioner registry under § 1181.26 (relating to removal of a practitioner from the practitioner registry) or if a patient's practitioner withdraws the patient's patient certification under § 1181.29(c), a medical marijuana cardholder shall submit a new application for an identification card within 90 days of receiving written notice from the Department or prior to the expiration date on the identification card, whichever is sooner.

§ 1191.31. Obtaining medical marijuana from a dispensary.

- (a) A medical marijuana cardholder may only obtain medical marijuana product from a dispensary.
- (b) A medical marijuana cardholder may only obtain medical marijuana product from a dispensary based upon

the recommendation in a patient certification that has not been revoked under § 1181.29 (relating to revocation of a patient certification) and that may be accessed by a dispensary through the electronic tracking system.

- (c) A medical marijuana cardholder may not obtain or possess any of the following:
- (1) A different form or greater quantity of medical marijuana product, if any, from that indicated on the patient certification.
- (2) Subject to paragraph (1) and subsection (d), a greater quantity of medical marijuana product than a 30-day supply.
- (3) Medical marijuana product that has otherwise been dispensed by a dispensary in violation of § 1161.24 (relating to limitations on dispensing).
- (d) Notwithstanding subsection (c)(2), during the last 7 days of any 30-day period, a patient may obtain and possess a 30-day supply for the subsequent 30-day period.

§ 1191.32. 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. Upon reaching majority, a minor patient who has been issued a medical marijuana patient authorization letter will be entitled to

- receive an identification card upon application under § 1191.25 (relating to application for, and issuance of, identification cards).
- (b) The Department may issue a medical marijuana patient authorization letter to an adult patient.
- (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.

§ 1191.33. Appeals.

Chapter 5 of 2 Pa.C.S. (relating to practice and procedure) applies to all actions of the Department under this chapter constituting an adjudication as defined in 2 Pa.C.S. § 101 (relating to definitions).

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