

RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 1131]

Medical Marijuana; Safe Harbor Letter for Minors with a Serious Medical Condition; Temporary Regulations

The Department of Health (Department) is publishing temporary regulations in Chapter 1131 (relating to Safe Harbor Letter) 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 (CDL), the Regulatory Review Act (71 P.S. §§ 745.1—745.14) and sections 204(b) and 301(10) of Commonwealth Attorneys Act (71 P.S. §§ 732-204(b) and 732-301(10)). The Department will be periodically publishing temporary regulations regarding various sections of the act.

These temporary regulations pertain to section 2106 of the act (35 P.S. § 10231.2106), regarding a parent or guardian of a minor under 18 years of age lawfully obtaining medical marijuana from another state, territory of the United States or any other country to be administered to the minor. These temporary regulations will expire on May 17, 2018, or upon the Department's publication in the *Pennsylvania Bulletin* that the Commonwealth's Medical Marijuana Program has been implemented, whichever comes first.

Interested persons are invited to submit written comments, suggestions or objections regarding the temporary regulations to Sunny D. Podolak, Bureau of Community Health Systems, Department of Health, Room 628, Health and Welfare Building, 625 Forester Street, Harrisburg, PA 17120, (717) 547-3085, spodolak@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 (800) 654-5984 (TT). Persons who require an alternative format of this document may contact Sunny D. Podolak so that necessary arrangements may be made.

Sections 1131.1—1131.7 are effective upon publication of this temporary rulemaking and expire as set forth in § 1131.7 (relating to sunset provision).

KAREN M. MURPHY, PhD, RN,
Secretary

Fiscal Note: 10-198. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IX. MEDICAL MARIJUANA

Chap. 1131. SAFE HARBOR LETTER

CHAPTER 1131. SAFE HARBOR LETTER

Sec.

- 1131.1. Definitions.
- 1131.2. Medical marijuana from outside this Commonwealth.
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- 1131.5. Penalties and sanctions.
- 1131.6. Confidentiality.
- 1131.7. Sunset provision.

§ 1131.1. Definitions.

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).

Applicant—One of the following who intends to obtain and administer medical marijuana to a minor under this chapter:

- (i) A parent.
- (ii) A legal guardian.
- (iii) A caregiver.
- (iv) An appropriate individual approved by the Department under section 506 of the act (35 P.S. § 10231.506).

Caregiver—An appropriate individual approved by Department under § 1131.2(c)(1) (relating to medical marijuana from outside this Commonwealth).

Certified medical use—The acquisition, possession, use or transportation of medical marijuana by a minor, or the acquisition, possession, delivery, transportation or administration of medical marijuana by the applicant, for use as part of the treatment of the minor's serious medical condition.

Department—The Department of Health of the Commonwealth.

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

Legal guardian—An individual lawfully invested with the power, and charged with the obligation, of taking care of and managing the property and rights of an individual under 18 years of age.

Medical marijuana—Marijuana used for a certified medical use by a minor with a serious medical condition, limited to the following forms:

- (i) Pill.
- (ii) Oil.
- (iii) Topical forms, including gel, creams and ointments.

(iv) A form medically appropriate for administration by vaporization or nebulization, excluding dry leaf or plant form.

- (v) Tincture.
- (vi) Liquid.

Medical Marijuana Program—The program enacted and administered by the Department under the act.

Minor—A patient under 18 years of age under the treatment of a physician for a serious medical condition under section 2106 of the act (35 P.S. § 10231.2106) who is a resident of this Commonwealth.

Parent—The natural or adoptive mother or father of a minor.

Safe Harbor Letter—A letter provided by the Department to an applicant under section 2106 of the act and this chapter that allows the applicant to administer medical marijuana to a minor in this Commonwealth.

Serious medical condition—One of the following conditions for which a minor may be permitted to use medical marijuana in this Commonwealth:

- (i) Cancer.
- (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 spinal cord with objective neurological indication of intractable spasticity.
- (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 in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective.
- (xvii) Autism.

§ 1131.2. Medical marijuana from outside this Commonwealth.

(a) *Application for Safe Harbor Letter.* An applicant may apply to the Department for a Safe Harbor Letter allowing the applicant to administer medical marijuana to a minor in this Commonwealth regardless of whether the medical marijuana was obtained from outside this Commonwealth as specified by section 2106 of the act (35 P.S. § 10231.2106).

(b) *Limitation.* The medical marijuana obtained from outside this Commonwealth is limited to the form of medical marijuana lawful in this Commonwealth as specified in the act.

(c) *Approval of caregiver.*

(1) The Department may approve a caregiver for a minor under one of the following circumstances:

- (i) The minor does not have either a parent or legal guardian.
- (ii) The minor is married to an individual under 21 years of age.
- (iii) A parent or legal guardian is not appropriate or available under the act or this chapter.

(2) An individual who is under 21 years of age may not be a caregiver to a minor unless:

- (i) The caregiver is married to the minor.
- (ii) An applicant makes a sufficient showing to the Department under section 507 of the act (35 P.S. § 10231.507).

§ 1131.3. Application.

(a) An applicant shall submit an application for a Safe Harbor Letter under this chapter on a form provided by the Department under subsection (d), and shall include the following information and any other information deemed necessary by the Department:

- (1) The name, address and date of birth of the following:
 - (i) The minor.
 - (ii) The applicant.
- (2) The minor’s state and county of birth, if the minor was not born in this Commonwealth.
- (3) The relationship of the applicant to the minor.
- (4) A copy of legal guardianship papers, if the applicant is a legal guardian.
- (5) A copy of legal proof of marriage, if the applicant is under 21 years of age and the minor’s spouse.
- (6) The applicant’s proof of residency by submitting one of the following:
 - (i) A Pennsylvania driver’s license.
 - (ii) A Department of Transportation-issued identification card.
 - (iii) Another form of identification that contains a photo and is approved by the Department in the application.
- (7) The applicant’s criminal history record information obtained from the Pennsylvania State Police or its authorized agent.
- (8) A written statement from a licensed physician in this Commonwealth listing the serious medical condition of the minor, the physician’s name, address of practice, telephone number and State license number.

(9) An applicant shall verify that the applicant will obtain the medical marijuana lawfully in another state.

(b) The applicant shall complete every required section of the application before it will be considered by the Department.

(1) If the Department deems an application submitted by an applicant to be incomplete, the Department will notify the applicant in writing of the factors for which further documentation is required.

(2) The applicant shall have 30 days from the mailing date of the notification to submit the additional material to the Department or the Department will deem the application as denied and the applicant will be required to submit a new application.

(c) The applicant shall certify as part of the application that the applicant understands and agrees to the following:

(1) Marijuana is a prohibited Schedule I controlled substance under Federal law.

(2) Participation in the Medical Marijuana Program is permitted only to the extent provided by the act and this chapter.

(3) An activity not sanctioned by the act or this chapter is a violation of State law.

(4) Growing, distributing or possessing marijuana in any capacity, except through a Federally-approved research program, is a violation of Federal law.

(5) Improper use or acquisition of medical marijuana may be a violation of State or Federal law.

(6) Participation in the Medical Marijuana Program does not authorize a person to violate Federal or State law and does not provide immunity from or affirmative defense to arrest or prosecution under Federal or State law except as provided under the act.

(7) An applicant, physician or minor shall indemnify, hold harmless and defend the Commonwealth for any and all civil or criminal penalties resulting from participation in the Medical Marijuana Program, including obtaining medical marijuana from outside this Commonwealth as set forth in section 2106 of the act (35 P.S. § 10231.2106).

(d) The applicant shall agree to and accept the limitations of liability and the requirements to indemnify, hold harmless and defend the Commonwealth by certifying that the applicant understands and agrees to the following:

(1) *Limitation of liability.* The Commonwealth is not liable to the state or entity from which the parent, guardian or caregiver obtained medical marijuana, the physician who provided a statement listing the serious medical condition of the minor, a caregiver of the minor, family members or guests for any damage, injury, accident, loss, compensation or claim, based on, arising out of or resulting from the growing, processing, dispensing, transportation or sale of medical marijuana to the applicant or minor, including, but not limited to, the following:

- (i) Arrest.
- (ii) Seizure of persons or property, or both.
- (iii) Prosecution under State or Federal law by State or Federal prosecutors.
- (iv) Fire, robbery, theft, mysterious disappearance or any other casualty.
- (v) The actions of any other permittees, registrants or persons.

(2) *Criminal prosecution.* The United States Congress has determined that marijuana is a controlled substance. Growing, distributing, transporting, possessing and using marijuana in any capacity, except as part of a Federally-authorized research program, is a violation of Federal law. The Pennsylvania General Assembly has placed marijuana in Schedule I of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144). Growing, distributing, transporting, possessing and

using marijuana is a violation of State law, except as specifically set forth in the act and this part.

(e) An application shall be obtained and submitted as required by the Department.

(f) The application must include a notice that a false statement by the applicant is punishable under the application provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

§ 1131.4. Validity of Safe Harbor Letter.

(a) The Safe Harbor Letter will be valid from the date of issuance by the Department until May 17, 2018, or unless any of the following occurs:

- (1) The minor reaches 18 years of age.
- (2) The minor dies.
- (3) The applicant dies or is no longer capable of carrying out the applicant's responsibilities.
- (4) The minor changes physicians.
- (5) The minor's physician knows or has reason to know that the minor no longer suffers from a serious medical condition and that use of medical marijuana would not be medically indicated.
- (6) The minor establishes residency in another state.
- (7) The applicant receives notice under subsection (f).

(b) The applicant or physician, or both, shall notify the Department in writing immediately upon knowledge of any change in the information in the original application and upon the occurrence of an event listed in subsection (a). The applicant shall return the invalid Safe Harbor Letter to the Department.

(c) A new application shall be submitted to the Department under the following circumstances:

- (1) The minor changes physicians. The application must include a written statement from the new physician that the minor suffers from a serious medical condition and state the nature of that condition.
- (2) The applicant is no longer capable of carrying out his responsibilities under section 2106 of the act (35 P.S. § 10231.2106) or this chapter. The new applicant shall submit an application including his relevant information.
- (3) The applicant has not submitted information within 30 days under § 1131.3(b)(2) (relating to application).

(d) The new application shall be submitted to the Department within a reasonable time period of the occurrence of the triggering event.

(e) The submission of a new application will not be considered to be effective notice under subsection (b).

(f) In the event that the Commonwealth's Medical Marijuana Program becomes effective prior to the expiration of Safe Harbor Letters, the Department will publish notice in the *Pennsylvania Bulletin* that Safe Harbor Letters will be invalid as of the effective date of the regulations. Individuals wishing to participate in the Medical Marijuana Program shall obtain the requisite identification cards and registrations under the act and this part.

(g) In the event that the Commonwealth's Medical Marijuana Program becomes effective prior to the expiration of Safe Harbor Letters, the Department will publish notice in the *Pennsylvania Bulletin* that Safe Harbor Letters will be invalid as of the effective date of the regulations. Individuals wishing to participate in the Medical Marijuana Program shall obtain the requisite identification cards and registrations under the act and this part.

§ 1131.5. Penalties and sanctions.

(a) In addition to the penalties in sections 1301—1309 of the act (35 P.S. §§ 10231.1301—10231.1309), the Department may deny, revoke or suspend a Safe Harbor Letter if the Department has evidence of the following:

(1) A conviction of a criminal offense that occurred within the 5 years relating to the sale or possession of drugs, narcotics or controlled substances.

(2) A history of drug abuse.

(3) A history of diversion of a controlled substance or illegal drugs.

(4) Falsified information on the application.

(5) A conviction of a crime of moral turpitude, such that the Department would not be able to find the applicant of good moral character.

(6) An intentional, knowing or reckless violation of a provision of the act or this chapter.

(b) An applicant whose Safe Harbor Letter is denied, suspended or revoked under subsection (a)(1) or (3)—(6) may be prohibited from participating in the Medical Marijuana Program for 5 years.

(c) 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).

§ 1131.6. Confidentiality.

Information obtained by the Department regarding a minor and applicant under this chapter is confidential and not subject to public disclosure, including disclosure under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104), including the following:

(1) Individual identifying information of minors or an applicant.

(2) Information regarding the minor’s serious medical condition, including the physician’s written statements.

§ 1131.7. Sunset provision.

This chapter expires upon the earlier of the following:

(1) May 17, 2018.

(2) Upon publication of a notice in the *Pennsylvania Bulletin*.

[Pa.B. Doc. No. 16-1066. Filed for public inspection June 24, 2016, 9:00 a.m.]