

RULE ADOPTIONS

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LAW AND PUBLIC SAFETY

DIVISION OF CONSUMER AFFAIRS

BOARD OF MEDICAL EXAMINERS

Adopted New Rules: N.J.A.C. 13:35-7A

Compassionate Use Medical Marijuana

Proposed: November 15, 2010 at 42 N.J.R. 2728(a).

Adopted: October 12, 2011 by Paul Jordan, M.D., President, Board of Medical Examiners.

Filed: November 7, 2011 as R.2011 d.292, with substantial changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 24:6I-1 et seq. (P.L. 2009, c. 307).

Effective Date: December 5, 2011.

Expiration Date: May 3, 2018.

## Summary of Public Comments and Agency Responses:

The Board of Medical Examiners (Board) received comments on the notice of proposal from the following:

1. Justin Escher Alpert;
2. Carolyn Torre, R.N., M.A., A.P.N., Director, Regulatory Affairs, New Jersey State Nurses Association; and
- [page=3192] 3. Ken Wolski, R.M., M.P.A., Executive Director, Coalition for Medical Marijuana - New Jersey, Inc.

1. COMMENT: Ms. Torre, on behalf of the New Jersey State Nurses Association, and Mr. Alpert, expressed concerns regarding various aspects of proposed new rules N.J.A.C. 8:64, promulgated by the Department of Health and Senior Services to implement the Compassionate Use Medical Marijuana Act.

RESPONSE: The commenters' concerns are more appropriately directed to the Department of Health and Senior Services as they relate to the Department's proposed new rules N.J.A.C. 8:64. The Board notes that the commenters did not raise any objections to the Board's proposed new rules N.J.A.C. 13:35-7A.5.

2. COMMENT: Mr. Wolski, on behalf of the Coalition for Medical Marijuana - New Jersey, Inc., urged the Board to declare that the Compassionate Use Medical Marijuana Act effectively rescheduled marijuana in New Jersey; noting that passage of the Act is inconsistent with marijuana's continued inclusion in New Jersey's list of Schedule I drugs. In addition, the commenter objected to the requirement in proposed new rule N.J.A.C. 13:35-7A.3 that physicians possess an active controlled dangerous substances (CDS) registration in order to authorize the medical use of marijuana, noting that a CDS registration is irrelevant for participating in the distribution of a Schedule I drug. The commenter believes this requirement to be a "meaningless bureaucratic addition" to an overly restrictive set of regulations.

RESPONSE: In enacting the Compassionate Use Medical Marijuana Act, the New Jersey Legislature did not reschedule marijuana. In creating this limited exception for marijuana's lawful use in New Jersey, the Legislature did so, mindful of the drug's current status under the New Jersey Controlled Dangerous Substances Act. See N.J.S.A. 24:6I-2 (noting that marijuana shall have the same meaning under the Compassionate Use Medical Marijuana Act as under the New Jersey Controlled Dangerous Substances Act). Therefore, the Board believes that requiring physicians to possess an active CDS registration in order to participate in the distribution of marijuana for medical purposes, is reasonable and consistent with the classification of marijuana as a Schedule I medication under the New Jersey Controlled Dangerous Substances Act, N.J.S.A.

24:21-2. The Board, therefore, declines to amend N.J.A.C. 13:35-7A.3 to eliminate this requirement.

#### Summary of Agency-Initiated Changes:

Following the publication of the notice of proposal, the New Jersey Senate introduced a concurrent resolution (SCR 140), seeking, in part, to declare proposed new rule N.J.A.C. 13:35-7A.5(c)3 inconsistent with the Compassionate Use Medical Marijuana Act. According to the concurrent resolution, the new rule would require physicians to "periodically attempt to stop a sick or dying patient's medical use of marijuana, decrease the quantity authorized, or try other drugs or treatment modalities" in contravention of the Act. In addition, following publication of the notice of proposal, numerous news media articles, referring to the Board's proposed new rules, reported that the rules would require physicians to "wean" dying patients off medical marijuana.

The Board believes that N.J.A.C. 13:35-7A.5(c), as proposed, does not require a physician to stop a patient's medical use of marijuana. Rather, the requirements set forth in N.J.A.C. 13:35-7A.5(c) and (d), are intended to establish minimum standards of practice that a physician must adhere to as part of his or her ongoing obligations for treatment of the patient's underlying debilitating medical condition, and the assessment of the patient's response to the use of medical marijuana in connection with such treatment. The Board did not intend that a patient who is achieving desired treatment benefits associated with medical marijuana, and who is not experiencing any untoward or significant, negative side effects as a result of marijuana use, should have his or her medical marijuana treatment interrupted. The Board believes that this intent is clearly reflected in N.J.A.C. 13:35-7A.3(c)3 of the rule as originally proposed. The rule provides that a physician must make reasonable efforts to stop the medical use of marijuana, decrease the quantity authorized or try other drugs or treatment modalities "unless clinically contraindicated."

The Board, however, believes that additional clarification to N.J.A.C. 13:35-7A.3(c) and (d) is necessary in order to eliminate confusion that may exist among authorizing physicians, the patients who may choose to avail themselves of medical marijuana in the future, and members of the general public, about a patient's continued use of medical marijuana when treatment objectives are being met and the patient is not experiencing any untoward side effects.

As changed upon adoption, N.J.A.C. 13:35-7A.3(c) continues to require a physician to assess the patient's condition, at a minimum, once every three months, including the patient's progress toward treatment objectives. Subsection (c) continues to require a physician to assess the patient for physical or psychological problems associated with marijuana use. The changed language, however, expressly requires the physician's assessment to include whether the patient is achieving the therapeutic results intended and whether the patient has developed significant

untoward side effects. As changed, the rule provides that if the physician determines that the patient is achieving treatment objectives, and is not experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician may continue the patient's treatment with medical marijuana without alteration. The Board has changed subsection (d) on adoption to clarify that if the patient is experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician must modify the patient's medical marijuana dosage or mode of delivery, undertake a trial of other drugs or treatment modalities, or discontinue the use of medical marijuana. Subsection (d) continues to require a physician to consider referring the patient for independent evaluation or treatment when treatment objectives are not being met.

The Division is also correcting the cross-references in N.J.A.C. 13:35-7A.6, which incorrectly referred to the Division's rules at N.J.A.C. 13:45A-32 rather than N.J.A.C. 13:45A-33, which are the Compassionate Use Medical Marijuana rules of the Division.

#### Federal Standards Statement

A Federal standards analysis is not required because the adopted new rules are being implemented pursuant to the New Jersey Compassionate Use Medical Marijuana Act, N.J.S.A. 24:6I-1 et seq. Under existing Federal law, the manufacture, possession, sale or distribution of marijuana is prohibited. See 21 U.S.C. §§ 841 et seq. States, however, are not required to enforce Federal law. In enacting the New Jersey Compassionate Use Medical Marijuana Act, the New Jersey Legislature found that compliance with the Act does not put the State of New Jersey in violation of Federal law. See N.J.S.A. 24:6I-2.

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks \*thus\*; deletions from proposal indicated in brackets with asterisks \*[thus]\*):

### SUBCHAPTER 7A. COMPASSIONATE USE MEDICAL MARIJUANA

#### 13:35-7A.1 Purpose and scope

(a) The rules in this subchapter implement certain provisions of the New Jersey Compassionate Use Medical Marijuana Act, P.L. 2009, c. 307.

(b) The rules in this subchapter shall apply to physicians who provide certifications and written instructions for patients seeking marijuana for medical use pursuant to rules adopted by the Board and by the Department of Health and Senior Services.

#### 13:35-7A.2 Definitions

The following words and terms when used in this subchapter shall have the following meanings, unless the context indicates otherwise.

"Bona fide physician-patient relationship" means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient's debilitating medical condition, consistent with the requirements of N.J.A.C. 13:35-7A.5. For purposes of this definition, "ongoing responsibility" means:

1. The physician-patient relationship has existed for at least one year;
2. The physician has seen and/or assessed the patient for the debilitating medical condition on at least four visits; or
3. The physician assumes responsibility for providing management and care of the patient's debilitating medical condition after conducting a comprehensive medical history and physical examination, including a personal review of the patient's medical record maintained by other treating physicians reflecting the patient's reaction and response to conventional medical therapies.

[page=3193]"Certification" means a statement signed by a physician with whom a patient has a bona fide physician-patient relationship, which attests to the physician's authorization for the patient to be registered to use marijuana.

"Debilitating medical condition" means:

1. One of the following conditions, if resistant to, or if the patient is intolerant to, conventional medical therapy: seizure disorder, including epilepsy; intractable skeletal muscular spasticity; or glaucoma;
2. One of the following conditions, if severe or chronic pain, severe nausea or vomiting, cachexia or wasting syndrome results from the condition or its treatment: positive status for human immunodeficiency virus, acquired immune deficiency syndrome or cancer;
3. Amyotrophic lateral sclerosis, multiple sclerosis, terminal cancer, muscular dystrophy or inflammatory bowel disease, including Crohn's disease;
4. Terminal illness, if the physician has determined a prognosis of less than 12 months of life; or
5. Any other medical condition or its treatment that is approved by the Department of Health and Senior Services by rule.

"Medical use of marijuana" means the acquisition, possession, transport or use of marijuana or paraphernalia by a qualified patient registered with the Department of Health and Senior Services under P.L. 2009, c. 307.

#### 13:35-7A.3 Requirement for physician participation

(a) A physician shall provide a certification and written instructions for a patient for the medical use of marijuana only if:

1. The physician holds an active New Jersey license in good standing issued by the Board and possesses an active controlled dangerous substances registration issued by the Division of Consumer Affairs that is not subject to limitation; and

2. The physician has a bona fide physician-patient relationship with the patient.

#### 13:35-7A.4 Certification requirements

(a) Prior to issuing a certification for the medical use of marijuana, the physician shall have conducted a comprehensive medical history and physical examination of the patient to determine whether the patient suffers from a debilitating medical condition that qualifies the patient to receive marijuana pursuant to N.J.S.A. 24:6I-3.

(b) The certification shall be signed and dated by the physician and shall attest to the physician's authorization for the patient to be registered with the Department of Health and Senior Services for the medical use of marijuana. If authorized by the Department of Health and Senior Services, the certification shall be electronically transmitted to the Department of Health and Senior Services. The certification shall include the following information:

1. Physician name, address and telephone number;

2. Physician license number and CDS registration number;

3. Patient name, address, telephone number and date of birth;

4. If applicable, caregiver name, address, telephone number and date of birth;

5. Diagnosis of debilitating medical condition; and

6. Any other information required by the Department of Health and Senior Services by rule.

(c) Prior to issuing a certification for the medical use of marijuana for a minor patient, a physician shall:

1. Obtain written confirmation from a physician trained in the care of pediatric patients and from a psychiatrist, establishing that, in their respective professional opinions, following review of the minor patient's medical record or examination of the minor patient, the minor patient is likely to receive therapeutic or palliative benefits from the medical use of marijuana to treat or alleviate symptoms associated with his or her debilitating medical condition. If the certifying physician is trained in the care of pediatric patients, he or she shall only be required to obtain written confirmation from a psychiatrist; and

2. Explain the potential risks and benefits of the medical use of marijuana to the minor patient and to a parent, guardian or person having legal custody of the minor patient. Such explanation shall be documented in the minor patient's medical record.

13:35-7A.5 Written instruction requirements; reassessment; records

(a) A physician may provide written instructions for the medical use of marijuana for a qualified patient registered with the Department of Health and Senior Services, provided the requirements in this section are satisfied. If authorized by the Department of Health and Senior Services, the physician may provide the written instruction by electronic or other means directly to an alternative treatment center on behalf of a registered qualifying patient.

(b) The physician's written instructions shall include the following information:

1. Physician name, address and telephone number;

2. Physician license number and CDS registration number;
3. Patient name, address, telephone number, date of birth and registry identification number;
4. If applicable, caregiver name, address, telephone number, date of birth and registry identification number;
5. Name of the permitted alternative treatment center;
6. Quantity of marijuana to be dispensed; and
7. Any other information required by the Department of Health and Senior Services by rule.

\*[(c) A physician authorizing the medical use of marijuana shall:

1. Review, at a minimum of every three months, the course of treatment, any new information about the patient's debilitating medical condition and the patient's progress toward treatment objectives;
2. Remain alert to problems associated with physical and psychological dependence; and
3. Periodically make reasonable efforts, unless clinically contraindicated, to stop the medical use of marijuana, decrease the quantity authorized or try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.]\*

\*[(c) A physician authorizing the medical use of marijuana shall review, at a minimum of every three months, the course of treatment for the patient's debilitating medical condition, and the

patient's progress toward treatment objectives as a result of the use of medical marijuana, including whether the patient is achieving the therapeutic results intended, has developed significant untoward side effects, or is experiencing any physical or psychological problems associated with marijuana use. If the physician determines that the patient is achieving treatment objectives, and is not experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician may continue the patient's treatment with medical marijuana without alteration.\*

\*[(d) If treatment objectives are not being met, the physician shall:

1. Assess the appropriateness of continued treatment with marijuana or undertake a trial of other drugs or treatment modalities; and]\*

\*(d) If treatment objectives for the patient's debilitating medical condition are not being met as a result of the use of medical marijuana, or the patient is experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician shall:

1. Modify the dosage of medical marijuana or mode of delivery authorized, provided the authorized amount does not exceed two ounces in a 30-day period consistent with (g) below, undertake a trial of other drugs or treatment modalities, or discontinue the use of medical marijuana; and\*

2. Consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

(e) The physician shall remain alert to the possibility that marijuana may be misused or diverted. A physician issuing written instructions for a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the physician and the patient concerning the medical use of marijuana and consequences for misuse.

(f) The physician shall keep accurate and complete records that include:

1. The medical history and physical examination of the patient;
  
2. The diagnosis of the debilitating medical condition, including the patient's symptoms and their severity and the patient's reaction and [page=3194] response to conventional medical therapies, which qualify the patient for the medical use of marijuana;
  
3. Other evaluations and consultations;
  
4. Treatment plan objectives;
  
5. Evidence of informed consent. In obtaining informed consent, the physician shall advise the patient about the lack of scientific consensus for the medical use of marijuana, its sedative properties and the risks for addiction;
  
6. Treatments and other drugs prescribed or provided;
  
7. Any agreements with the patient; and
  
8. Periodic reviews conducted.

(g) A physician shall not issue written instructions authorizing a patient to receive more than two ounces of marijuana in a 30-day period.

(h) A physician may issue multiple written instructions at one time authorizing the patient to receive a total of up to a 90-day supply of marijuana, provided that the following conditions are met:

1. Each separate set of instructions is issued for the treatment of the patient's documented debilitating medical condition;
  2. Each separate set of instructions indicates the earliest date on which the alternative treatment center may dispense the marijuana, except for the first dispensation if it is to be filled immediately; and
  3. The physician has determined that providing the patient with multiple instructions in this manner does not create an undue risk of diversion or abuse.
- (i) The physician shall keep a copy of the patient's, or if applicable, the caregiver's registry identification card, in the patient's medical record.
- (j) If the physician determines that the patient's underlying debilitating medical condition no longer exists or that the patient's continued use of marijuana is no longer appropriate, the physician shall notify the Department of Health and Senior Services of his or her findings.

#### 13:35-7A.6 Duty to report information to the Division

- (a) A physician shall comply with all requests for information from the Division of Consumer Affairs concerning the issuance of certifications and written instructions for the medical use of marijuana as provided in N.J.A.C. 13:45A-\*[32]\*\*33\*.
- (b) Failure on the part of a physician to comply with the requirements of N.J.A.C. 13:45A-\*[32]\*\*33\* may subject the physician to disciplinary action pursuant to N.J.S.A. 45:1-21 et seq.