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RULE ADOPTIONS

LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
NEW JERSEY STATE BOARD OF OPTOMETRISTS

Adopted Concurrent New Rule: N.J.A.C. 13:38-2.5

Limitations on Prescribing, Administering, or Dispensing of Controlled Dangerous Substances, and Special Requirements for Management of Acute and Chronic Pain

Proposed: March 20, 2017, at 49 N.J.R. 562(a).

Adopted: April 28, 2017, by Christopher S. Porrino, Attorney General, State of New Jersey and April 25, 2017, by Gigette Collazo Harfst, O.D., Vice President, New Jersey State Board of Optometrists.

Filed: April 28, 2017, as R.2017 d.111, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:1-17.b and 45:12-4.

Effective Date: April 28, 2017, Concurrent Adopted New Rule;
June 5, 2017, Changes Upon Adoption.

Expiration Date: March 15, 2019.

Summary of Public Comments and Agency Responses:

The official comment period ended April 19, 2017. The Attorney General and the New Jersey State Board of Optometrists (Board) received comments from the following:

1. William J. Ference, OD, President, New Jersey Society of Optometric Physicians;
2. Robert Carullo, Executive Director, SMART (Strengthening the Mid-Atlantic Region for Tomorrow) Congressional Initiative;
3. Debbie Burrell, Board Member & Healthcare Chair, Strengthening the Mid-Atlantic Region for Tomorrow, and President, Burrell International Group, LLC; and
4. Mandi S. Love, Esq., RN-BC, CLNC.

1. COMMENT: One commenter expressed support for the proposed regulations.

RESPONSE: The Attorney General and the Board thank the commenter for its support.

2. COMMENT: One commenter recommended amending the wording of N.J.A.C. 13:38-2.5(b)2 to allow the optometric physician's professional judgment to determine if a

comprehensive eye examination is required. The commenter noted that performing a comprehensive eye examination may not be an appropriate procedure in every circumstance as the patient may be suffering from trauma to the eye and a comprehensive examination may not be possible. The commenter suggested changing the wording to "appropriate physical examination."

RESPONSE: The Attorney General and the Board agree with the commenter that a comprehensive eye examination may not be appropriate in every circumstance. Upon adoption, the Attorney General and Board will change N.J.A.C. 13:38-2.5(b)2 to change "comprehensive eye examination" to "appropriate ocular evaluation." Additional public notice of this change is not required because it does not change the effect of this rule. The change provides clarity as to the type of examination necessary based upon the professional standard of care and does not increase the burden on optometrists.

3. COMMENT: Three commenters recommended including a requirement that prescribers co-prescribe naloxone, an opioid overdose antidote. The commenters noted that a key lifesaving part of the Centers for Disease Control and Prevention (CDC) guidelines includes co-prescribing naloxone or opioid antagonists for at-risk patients. The commenters stated that co-prescribing naloxone has increasingly gained support across a broad range of stakeholders, including Federal agencies, medical professional associations, and patient advocates as an effective way of increasing access to naloxone and tackling the opioid addiction crisis. The commenters also noted that, in 2016, both the American Medical Association and the CDC issued guidelines that called upon physicians to offer naloxone when factors that increase risk for opioid overdose, such as a history of overdose, substance use disorder, high-dose opioids, or opioids prescribed concurrently with benzodiazepines, are present.

RESPONSE: The Attorney General and Board agree that opioid overdose antidotes are a meaningful way to save lives. The Overdose Prevention Act, N.J.S.A. 24:6J-1 et seq., governs the prescribing and dispensing of an opioid antidote, including naloxone hydrochloride. Under this act, an opioid antidote may be dispensed pursuant to a patient-specific prescription or via a standing order issued in accordance with the law. N.J.A.C. 13:38-2.5(f)7 specifies that for those patients being prescribed an opioid drug to treat chronic pain, the practitioner shall discuss the availability of an opioid antidote. In addition, the Board anticipates posting on its website frequently asked questions that will encourage a discussion about opioid antidotes. The Attorney General and the Board believe that mandating the co-prescribing of an opioid antidote for at-risk patients is beyond the scope of this rulemaking.

Summary of Agency-Initiated Changes:

The Attorney General and the Board are changing N.J.A.C. 13:38-2.5(d) to replace the reference of "first prescription" with "initial prescription" for consistency in using a defined term and to avoid any confusion caused by using the two different terms. This change does not require any additional public notice because it does not change the effect of this rule.

The Attorney General and the Board are changing N.J.A.C. 13:38-2.5(d)2 to remove reference to subparagraph (i) which was an artifact from a prior draft of the emergency adoption. This change does not require any additional public notice because it does not change the effect of this rule.

In addition, the Attorney General and the Board are changing N.J.A.C. 13:38-2.5(e) to include language to clarify that if a licensee has entered into a pain management agreement

with a patient prior to the issuance of the third prescription it is not necessary to enter into an additional pain management agreement. Additional public notice of this change is not required because it does not change the effect of this rule nor does it increase the burden on the licensed optometrists.

The Attorney General and the Board are changing N.J.A.C. 13:38-2.5(f)7 to delete "For those patients being prescribed an opioid drug to treat chronic pain," which is redundant due to the reference to "chronic pain" in subsection (f) itself.

Federal Standards Statement

A Federal standards analysis is not required because the adopted new rule is governed by N.J.S.A. 45:12-1 et seq. To the extent that the CDC Guideline may be viewed as establishing and setting forth Federal standards and requirements for the prescribing and dispensing of opioid drugs, the adopted new rule is consistent with these standards.

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

SUBCHAPTER 2. GENERAL RULES OF OPTOMETRIC PRACTICE

13:38-2.5 Limitations on prescribing, dispensing, or administering controlled dangerous substances; special requirements for management of acute and chronic pain

(a) The following words and terms when used in this section, shall have the following meanings, unless the context clearly indicates otherwise:

"Acute pain" means the pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the licensee reasonably expects to last only a short period of time. "Acute pain" does [page=1441] not include chronic pain, pain being treated as part of cancer care, hospice or other end of life care, or pain being treated as part of palliative care.

"Chronic pain" means pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause, it continues, either continuously or episodically.

"Initial prescription" means a prescription issued to a patient who:

1. Has never previously been issued a prescription for the drug or its pharmaceutical equivalent; or
2. Was previously issued a prescription for the drug or its pharmaceutical equivalent, and the date on which the current prescription is being issued is more than one year after the date the patient last used or was administered the drug or its equivalent. When determining whether a patient was previously issued a prescription for a drug or its pharmaceutical equivalent, the licensee shall consult with the patient, review prescription monitoring information, and, to the extent it is available to the licensee, review the patient's medical record.

"Licensee" means a licensed optometrist who is currently authorized to prescribe drugs in the course of professional practice, acting within the scope of practice of his or her professional license.

"Palliative care" means care provided to an individual suffering from an incurable progressive illness that is expected to end in death, which is designed to decrease the severity of pain, suffering, and other distressing symptoms, and the expected outcome of which is to enable the individual to experience an improved quality of life.

(b) When prescribing, dispensing, or administering controlled dangerous substances, a licensee shall:

1. Take a thorough history of the patient which reflects the nature, frequency, and severity of any pain, the patient's history of substance use or abuse, and the patient's experience with non-opioid medication and non-pharmacological pain management approaches;

2. Conduct *[a comprehensive eye examination]* ***an appropriate ocular evaluation***;

3. Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to section 8 of P.L. 2015, c. 74 (N.J.S.A. 45:1-46.1) and consider that information in accordance with N.J.A.C. 13:45A-35;

4. Develop a treatment plan, which identifies the objectives by which treatment success is to be evaluated, such as pain relief and improved function, and any further diagnostic evaluations or other treatments planned; and

5. Prepare a patient record that reflects the history, the findings on examination, any relevant PMP data, and the treatment plan, as well as:

i. The complete name of the controlled substance;

ii. The dosage, strength, and quantity of the controlled substance; and

iii. The instructions as to frequency of use.

(c) With respect to Schedule II controlled dangerous substances, unless the prescribing of opioids is subject to limitations as set forth in (g) below, a licensee may authorize a quantity not to exceed a 30-day supply, which shall be at the lowest effective dose as determined by the directed dosage and frequency of dosage. The prescribing of opioids in any schedule is subject to limitations as set forth in (g) below.

(d) Prior to issuing *[the first]* ***an initial*** prescription for a Schedule II controlled dangerous substance for pain or any opioid drug, a licensee shall discuss with the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, the reasons why the medication is being prescribed, the possible alternative treatments, and the risks associated with the medication. With respect to opioid drugs, the discussion shall include, but not be limited to, the risks of addiction, physical or psychological dependence, and overdose associated with opioid drugs and the danger of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants, and requirements for proper storage and disposal.

1. If the patient is under 18 years of age and is not an emancipated minor, the licensee shall have the discussion required in (d) above prior to the issuance of each subsequent prescription for any opioid drug that is a Schedule II controlled dangerous substance.

2. *[In addition to the requirements of (i) below, the]* ***The*** licensee shall reiterate the discussion required in (d) above prior to issuing the third prescription of the course of

treatment for a Schedule II controlled dangerous substance for pain or any opioid drug.

3. The licensee shall include a note in the patient record that the required discussion(s) took place.

(e) At the time of*, **or prior to**,* issuance of the third prescription for a Schedule II controlled dangerous substance for pain or any opioid drug, the licensee shall enter into a pain management agreement with the patient. The pain management agreement shall be a written contract or agreement that is executed between a licensee and a patient, that is signed and dated prior to the issuance of the third prescription for the ongoing treatment of pain using a Schedule II controlled dangerous substance or any opioid drug, and which shall:

1. Document the understanding of both the licensee and the patient regarding the patient's pain management plan;

2. Establish the patient's rights in association with treatment, and the patient's obligations in relation to the responsible use, discontinuation of use, and storage and disposal of Schedule II controlled dangerous substances and any opioid drugs, including any restrictions on the refill or acceptance of such prescriptions from licensees and other prescribers;

3. Identify the specific medications and other modes of treatment, including physical therapy or exercise, relaxation, or psychological counseling, that are included as part of the treatment plan;

4. Specify the measures the licensee may employ to monitor the patient's compliance, including but not limited to, random specimen screens and pill counts; and

5. Delineate the process for terminating the agreement, including the consequences if the licensee has reason to believe that the patient is not complying with the terms of the agreement.

(f) When controlled dangerous substances are continuously prescribed for management of chronic pain, the licensee shall:

1. Review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives, and document the results of that review;

2. Assess the patient prior to issuing each prescription to determine whether the patient is experiencing problems associated with physical and psychological dependence, and document the results of that assessment;

3. Make periodic reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled dangerous substance, taper the dosage, try other drugs such as nonsteroidal anti-inflammatories, or utilize alternative treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence, and document, with specificity, the efforts undertaken;

4. Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to section 8 of P.L. 2015, c. 74 (N.J.S.A. 45:1-46.1) and consider that information in accordance with N.J.A.C. 13:45A-35;

5. Monitor compliance with the pain management agreement and any recommendations that the patient seek a referral and discuss with the patient any breaches that reflect that the patient is not taking the drugs prescribed or is taking drugs, illicit or prescribed by licensees or prescribers, and document within the patient's record the plan after that discussion;

6. Conduct random urine screens at least once every 12 months;

7. *[For those patients being prescribed an opioid drug to treat chronic pain, advise]*
Advise the patient, or the patient's parent or guardian if the patient is under 18 years of age and is not an emancipated minor, of the availability of an opioid antidote; and

8. Refer the patient to a pain management or addiction specialist for independent evaluation or treatment in order to achieve treatment objectives, if those objectives are not being met.

(g) A licensee shall not issue an initial prescription for an opioid drug for treatment of acute pain in a quantity exceeding a five-day supply as determined by the directed dosage and frequency of dosage. The initial prescription shall be for the lowest effective dose of immediate-release opioid drug. A licensee shall not issue an initial prescription for an opioid drug that is for an extended-release or long-acting opioid. No less than four days after issuing the initial prescription, upon request of the patient, a licensee may issue a subsequent prescription for an opioid drug [page=1442] for the continued treatment of acute pain associated with the condition that necessitated the initial prescription provided the following conditions are met:

1. The licensee consults (in person, via telephone, or other means of direct communication) with the patient;

2. After the consultation with the patient, the licensee, in the exercise of professional judgment, determines that an additional days' supply of the prescribed opioid drug is necessary and appropriate to the patient's treatment needs and does not present an undue risk of abuse, addiction, or diversion;

3. The licensee documents the rationale for the authorization in the patient record;

4. The subsequent prescription for an additional days' supply of the prescribed opioid drug is tailored to the patient's expected need at the stage of recovery, as determined under (g)2 above and any subsequent prescription for an additional days' supply shall not exceed a 30-day supply.

(h) When a licensee issues an initial prescription for an opioid drug for the treatment of acute pain, the licensee shall so indicate it on the prescription.

(i) The requirements for prescribing controlled dangerous substances set forth in (d) through (h) above shall not apply to a prescription for a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice, receiving palliative care, or is a resident of a long-term care facility, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

(j) Nothing in (g) above shall be construed to limit a licensee's professional judgment to authorize a subsequent prescription for an opioid drug in a quantity consistent with (g)4

above for the continued treatment of acute pain associated with the condition that necessitated the initial prescription.