

VOLUME 49, ISSUE 11
ISSUE DATE: **JUNE 5, 2017**
RULE ADOPTIONS

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

Adopted Concurrent Amendment: N.J.A.C. 13:30-8.18

Issuance of Prescriptions; 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. 547(a).

Adopted: April 28, 2017, by Christopher S. Porrino, Attorney General, State of New Jersey and April 25, 2017, by Nicholas DeRobertis, DMD, President, New Jersey State Board of Dentistry.

Filed: April 28, 2017, as R.2017 d.108, **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 45:6-3.

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

Expiration Date: January 5, 2018.

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 Dentistry (Board) received comments from the following:

1. Dr. Jason Lizzack;
2. Richard Fort;
3. Joff Masukawa, Principal, Diligentia Strategies;
4. Robert Carullo, Executive Director, SMART (Strengthening the Mid-Atlantic Region for Tomorrow) Congressional Initiative;
5. Debbie Burrell, Board Member & Healthcare Chair, Strengthening the Mid-Atlantic Region for Tomorrow, and President, Burrell International Group, LLC;
6. Mandi S. Love, Esq., RN-BC, CLNC; and

7. James Schulz, Jr., Director, Governmental and Public Affairs, New Jersey Dental Association.

1. COMMENT: One commenter supported limiting to five days the prescription of opioids for the treatment of acute pain. The commenter stated that he recognizes the addictive properties of opioids and the huge problem of opioid addiction in our country. The commenter, however, believes that opioids are a very important drug to help people become comfortable when they have severe dental pain and non-opioids do not sufficiently help, and would be concerned if the Attorney General and Board completely eliminate opioid prescriptions. The commenter also stated that he believes more of the problem is when prescribers prescribed opioids at several times the dosage than should be prescribed for chronic pain.

RESPONSE: The Attorney General and the Board thank the commenter for his support. P.L. 2017, c. 28, and the adopted amendments to N.J.A.C. 13:30-8.18 prohibit a practitioner from issuing an initial prescription for an opioid drug for the treatment of acute pain in a quantity exceeding a five-day supply, and require the prescription to be for the lowest effective dose of an immediate-releasing opioid drug. There is no intent to eliminate the prescribing of opioid medications, and the rule is not to be construed to limit a licensee's professional judgment to issue subsequent prescriptions for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription. Instead, the rule is intended to infuse into the licensee/patient relationship a need for consultation after the expected course of recovery and prior to issuing additional prescriptions for opioids.

2. COMMENT: One commenter opposed the five-day limitation for opioids because of concerns that patients who are legitimately in pain will not be prescribed the necessary medication for pain relief. The commenter stated that the law and proposed regulations result in prescribers not prescribing any pain medications because of fear of the Drug Enforcement Administration (DEA) investigating them and losing their career.

RESPONSE: The rule is not to be construed to limit a licensee's professional judgment to issue subsequent prescriptions for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription. The Centers for Disease Control and Prevention recommends that prescribers "should not prescribe additional opioids to patients 'just in case' pain continues longer than expected" but rather "should re-evaluate the subset of patients who experience severe acute pain that continues longer than the expected duration to confirm or revise the initial diagnosis and to adjust management accordingly." The rule, therefore, is intended to infuse into the licensee/patient relationship a need for consultation after the expected course of recovery and prior to issuing additional prescriptions.

3. COMMENT: Four 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. 13:30-8.18(h)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.

4. COMMENT: One commenter requested that the Attorney General and Board clarify and more clearly differentiate between the phrases "initial prescription," a defined term, and "first prescription [issued by the same licensee]," which is not a defined term. The commenter noted that, as defined in proposed N.J.A.C. 13:30-8.18(a), the term "initial prescription" means a prescription issued to a patient who:

1. Has never previously been issued a prescription for the drug or 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.

The commenter stated that, therefore, if a patient has been issued one or more prescriptions for a drug within the preceding year by a licensee, a prescription for the same drug by another practitioner would not, by [page=1431] definition, be treated as an "initial prescription." The commenter also stated that the proposed language at N.J.A.C. 13:30-8.18(i) limits to no more than five days the issuance of an "initial prescription" for an opioid drug for the treatment of acute pain. The rule further provides that "no less than four days after issuing the initial prescription, upon request of the patient, a licensee may issue a subsequent prescription." The commenter further stated that, based upon the definition of "initial prescription," those provisions would not apply to a patient who had received the same drug within the last year. The commenter does not believe that this was intended by the rulemaking. The commenter believes that this anomaly would be resolved if the words "initial prescription" were deleted and replaced by the words "first prescription by the same licensee."

RESPONSE: The Attorney General and Board agree that the use of "first prescription" is confusing. To avoid this confusion and to be consistent with the defined terms, upon adoption, the Attorney General and Board will change N.J.A.C. 13:30-8.18(f) to change "first prescription" to "initial prescription." The Attorney General and Board, however, decline to include language specifying that the prescription is by the same licensee. The adopted amendments establish mechanisms to protect the patient, which are triggered by the issuance of controlled dangerous substances prescriptions to the patient. The patient is not adequately protected if these mechanisms are only triggered based upon prescriptions issued by the same licensee, especially when the patient is under the care of different prescribers.

5. COMMENT: One commenter stated that because responsibilities, such as entry into a pain

management agreement, from which penalties or liabilities may flow are imposed upon licensees who issue "third prescriptions" for Schedule II drugs, it is especially important for a licensee to know what constitutes a "third prescription." To provide clarification, the commenter recommended that wherever this term is used, the Attorney General and Board include the language "by the same licensee."

RESPONSE: The Attorney General and the Board agree that "third prescription" is a term that needs to be defined and the Board will address this in a future rulemaking. The Attorney General and Board, however, decline to include language specifying that the prescription is by the same licensee. The adopted amendments establish mechanisms to protect the patient, which are triggered by the issuance of controlled dangerous substances prescriptions to the patient. The patient is not adequately protected if these mechanisms are only triggered based upon prescriptions issued by the same licensee, especially when the patient is under the care of different prescribers.

6. COMMENT: One commenter recommended deleting the words "initial prescription" from proposed N.J.A.C. 13:30-8.18(j), and replacing them with the words "first prescription by the same licensee." In addition, the commenter stated that it is unclear why this provision is necessary.

RESPONSE: The Attorney General and the Board note that P.L. 2017, c. 28 establishes how insurance plans will charge the co-payment, coinsurance, or deductible for an initial prescription of an opioid drug prescribed in accordance with the law. To determine which prescriptions are subject to the law's requirements and to ensure patients are properly charged these costs, the prescription for an opioid drug must reflect when it is for an initial prescription for the treatment of acute pain. The Attorney General and Board decline to change the wording as suggested by the commenter. (see the Response to Comment 4)

7. COMMENT: One commenter noted that, with respect to the urine screen requirement in proposed N.J.A.C. 13:30-8.18(h)6, it is not aware of any dental offices that "conduct" urine screens. Accordingly, the commenter requested that this requirement be amended or deleted.

RESPONSE: The Attorney General and Board decline to amend or delete N.J.A.C. 13:30-8.18(h)6 because they believe the use of random urine screens is an additional mechanism prescribers should use to assure that patients are complying with their prescribed treatment regimen when they are being treated for chronic pain. In addition, urine screenings enhance the way prescribers can be informed about the best medication choices for their patients and help to assure that diversion is not occurring.

8. COMMENT: One commenter suggested that, to assist dentists with the referral requirements of proposed N.J.A.C. 13:30-8.18(h)8, the Board and/or the **Division of Consumer Affairs** (Division) publish on their respective websites a list of pain management or addiction specialists.

RESPONSE: The Attorney General and Board decline to publish a list of specialists to whom dentists may refer their patients on the websites of the Division or Board. As part of current practice, dentists refer patients to different types of specialists and may use the same method to refer patients to pain management or addiction specialists.

9. COMMENT: One commenter recommended that the term "licensee" be defined as "a licensed dentist who possesses the appropriate permits and/or licenses to prescribe controlled dangerous substances in the course of professional practice."

RESPONSE: The Attorney General and Board decline to change the definition of "licensee" as suggested by the commenter. Under State and Federal law, a prescriber issuing a prescription for controlled dangerous substances must have the appropriate registrations.

Summary of Agency-Initiated Changes:

The Attorney General and the Board are changing N.J.A.C. 13:30-8.18(f)2 to remove reference to subsection (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.

The Attorney General and the Board are changing N.J.A.C. 13:30-8.18(g) 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 dentists.

The Attorney General and the Board are changing N.J.A.C. 13:30-8.18(h)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 the lead-in text of subsection (h) itself.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments are governed by N.J.S.A. 45:6-1 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 amendments are consistent with these standards.

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

SUBCHAPTER 8. GENERAL PROVISIONS

13:30-8.18 Issuance of prescriptions; NJPBs; 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 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 [page=1432] 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 they are available, review the patient's dental and medical records.

"Licensee" means a licensed dentist who is currently authorized to prescribe drugs in the course of professional practice.

"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) (No change in text.)

(c) Licensees issuing prescriptions for controlled dangerous substances shall comply with all State and Federal laws concerning the issuance of such prescriptions, including the requirements of the controlled dangerous substances rules set forth at N.J.A.C. 13:45H and the prescription monitoring program rules at N.J.A.C. 13:45A-35.

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

1. Take a thorough medical history of the patient, which reflects the nature, frequency, and severity of any pain being experienced before or after a dental procedure, 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 dental examination;

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 includes the nature, frequency, and severity of any pain expected after a dental procedure or associated with dental conditions and 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, with particular attention focused on determining the cause of the patient's pain; and

5. Include in the patient's dental record the medical history, including the information described in (d)1 above, 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.

(e) With respect to Schedule II controlled dangerous substances, unless the prescribing of opioids is subject to limitations as set forth in (i) 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 (i) below.

(f) 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 under (f) 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 (f) 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.

(g) 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.

(h) 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 other 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.

(i) 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 an 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 for the continued treatment of acute pain associated with the [page=1433] 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 his or her 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 (i)2 above and any subsequent prescription for an additional days' supply shall not exceed a 30-day supply.

(j) 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.

(k) The requirements for prescribing controlled dangerous substances set forth in (f) through (j) 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.

(l) Nothing in (i) 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 (i)4 above for the continued treatment of acute pain associated with the condition that necessitated the initial prescription.