54 N.J.R. 1170(b)

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RULE ADOPTIONS

Reporter

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Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF DENTISTRY

Administrative Code Citation

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

Text

Limitations on Prescribing, Administering, or Dispensing of Controlled Dangerous Substances, and Special Requirements for Management of Acute and Chronic Pain (Co-Prescribing Opioid Antidote)

Proposed: January 19, 2021, at 53 N.J.R. 107(a).

Notice of Proposed Substantial Changes Upon Adoption to Proposed Amendment: January 18, 2022, at 54 N.J.R. 115(a).

Adopted: April 6, 2022, by State Board of Dentistry, Steven C. Cohen, DMD, President.

Filed: May 18, 2022, as R.2022 d.071, **with substantial changes** to proposal after additional notice and public comment, pursuant to N.J.S.A. 52:14B-4.10.

Authority: N.J.S.A. 45:6-19.4; and P.L. 2017, c. 341 and P.L. 2021, c. 54.

Effective Date: June 20, 2022.

Expiration Date: April 3, 2025.

Summary of Public Comment and Agency Response:

The official comment period ended March 19, 2022. No comments were received.

Summary of Agency-Initiated Changes:

The New Jersey State Board of Dentistry (Board) is changing N.J.A.C. 13:30-8.18 to implement P.L. 2021, c. 54, which establishes the circumstances and conditions under which a health care practitioner must issue a prescription for an opioid antidote. In accordance with the new law, a licensed dentist must co-prescribe an opioid antidote whenever the dentist issues a prescription for an opioid drug that is a controlled dangerous substance and one of the following conditions exists: the patient has a history of substance use disorder, the prescription for the opioid drug is for a daily dose of more than 90 morphine milligram equivalents (MME), or the patient holds a current, valid prescription for a benzodiazepine that is a Schedule III or Schedule IV controlled dangerous substance. The statutory provisions differ from the Board's original notice of proposal by requiring the prescription for an opioid antidote whenever an opioid drug is prescribed, instead of when the practitioner continuously prescribes a controlled dangerous substance for the management of chronic pain. Additionally, the new law requires the co-prescribing of an opioid antidote if the patient has a history of substance abuse and modifies the threshold for the morphine milligram equivalents to require the co-prescribing of an opioid antidote where the MME exceeds--rather than equals or exceeds--90 MME. The new law also provides that the prescriber is not required to issue more than one prescription for an opioid antidote to a patient per year but may do so, either upon the patient's request or when the prescriber determines that there is a clinical or practical need for the additional prescription. To implement the new law, the Board is removing proposed new paragraph (h)8 (and the attendant technical change at paragraph (h)7) and to add new subsection (k). In addition, the Board is recodifying subsections (k) and (l) as new subsections (l) and (m), and changing recodified subsection (l) to reflect the addition of subsection (k). The Board is also changing subsection (a) to include a definition for the term "opioid antidote."

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., and 24:21-15.2.

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 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:

. . .

"Chronic pain" means pain that persists or recurs for more than three months.

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

- 1. (No change.)
- 2. Was previously issued a prescription for, or used or was administered, 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, or

used or was administered, 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.

. . .

"Opioid antidote" means any drug, regardless of dosage amount or method of administration, which has been approved by the United [page=1171] States Food and Drug Administration (FDA) for the treatment of an opioid overdose. "Opioid antidote" includes, but is not limited to, naloxone hydrochloride, in any dosage amount, which is administered through nasal spray or any other FDA-approved means or methods.

. . .

- (b)-(c) (No change.)
- (d) When prescribing, dispensing, or administering controlled dangerous substances, a licensee shall:
- 1.-2. (No change.)
- 3. Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to N.J.S.A. 45:1-46.1 and consider that information in accordance with N.J.A.C. 13:45A-35:
- 4.-5. (No change.)
- (e) (No change.)
- (f) Prior to issuing an initial prescription for a Schedule II controlled dangerous substance or any opioid drug in the course of treatment for acute pain, 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, including that opioids are highly addictive, even when taken as prescribed and used as directed, 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. (No change.)
- 2. The licensee shall reiterate the discussion required at (f) above prior to issuing a prescription at the outset of a course of treatment for chronic pain for a Schedule II controlled dangerous substance or any opioid drug.
- 3. (No change.)
- (g) Prior to the commencement of an ongoing course of treatment for chronic pain with a Schedule II controlled dangerous substance 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 commencement of an ongoing course of treatment for chronic pain using a Schedule II controlled dangerous substance or any opioid drug, and which shall:
- 1.-5. (No change.)
- (h) When controlled dangerous substances are continuously prescribed for management of chronic pain, the licensee shall:
- 1.-3. (No change.)
- 4. Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to N.J.S.A. 45:1-46.1 and consider that information in accordance with N.J.A.C. 13:45A-35;
- 5.-6. (No change.)

- 7. 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. Provide a prescription for an opioid antidote if the patient has one or more prescriptions totaling 90 morphine milligram equivalents or more per day, or is concurrently obtaining an opioid and a benzodiazepine, and document within the patient record the action taken; and]*

[9.] *8.* (No change in text.)

(i)-(j) (No change.)

- *(k) Except as provided at (k)1 below, when a licensee issues a prescription for an opioid drug that is a controlled dangerous substance to a patient, the licensee shall also issue the patient a prescription for an opioid antidote when the patient has a history of substance use disorders, the prescription for the opioid drug is for a daily dose of more than 90 morphine milligram equivalents, or the patient holds a current, valid prescription for a benzodiazepine drug that is a Schedule III or Schedule IV controlled dangerous substance.
- 1. A licensee shall not be required to issue more than one prescription for an opioid antidote to a patient per year.
- 2. Nothing at (k)1 above shall be construed to prohibit a licensee from issuing additional prescriptions for an opioid antidote to a patient upon the patient's request or when the licensee determines there is a clinical or practical need for the additional prescription.*
- *[(k)]* *(I)* The requirements for prescribing controlled dangerous substances set forth *[in]*
 at (f) through *[(j)]* *(k)* 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.

[(I)] *(m)* (No change in text.)

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