55 N.J.R. 110(b)

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RULE ADOPTIONS

Reporter
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Agency

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF MEDICAL EXAMINERS

Administrative Code Citation

Adopted Amendment: N.J.A.C. 13:35-7.6

Text

Limitations on Prescribing, Administering, or Dispensing of Controlled Dangerous Substances, and Special Requirements for Management of Acute and Chronic Pain: Physicians, Podiatrists, Physician Assistants, and Certified Nurse Midwives

Proposed: February 22, 2022, at 54 N.J.R. 333(a).

Adopted: July 13, 2022, by the State Board of Medical Examiners, Otto F. Sabando, D.O., President.

Filed: December 20, 2022, as R.2023 d.011, **without change**.

Authority: N.J.S.A. 45:9-2; and P.L. 2021, c. 54.

Effective Date: January 17, 2023.

Expiration Date: April 3, 2025.

Summary of Public Comment and Agency Response:

The official comment period ended April 23, 2022. **No comments were received.**

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Federal Standards Statement

A Federal standards analysis is not required because there are no Federal laws or standards applicable to the adopted amendment, which is governed by N.J.S.A. 45:9-1 et seq., and 24:21-15.2.

Full text of the adoption follows:

SUBCHAPTER 7. PRESCRIPTION, ADMINISTRATION, AND DISPENSING OF DRUGS

13:35-7.6 Limitations on prescribing, administering, or dispensing of 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:

. . .

"Opioid antidote" means any drug, regardless of dosage amount or method of administration, that has been approved by the United 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, that is administered through nasal spray or any other FDA-approved means or methods.

. . .

"Treatment plan" means a memorialization of the objectives by which treatment success is to be evaluated, including, when treating the patient for pain, the specific objectives for pain relief and improved physical and psychological function and any further diagnostic evaluations or other treatments planned, with particular focus on determining the cause of the patient's pain, and when treating chronic pain, the terms of the pain management agreement.

(b) When initiating the prescribing of, the dispensing of, or the administration of controlled dangerous substances, a practitioner shall:

1. (No change.)

2. Conduct a physical examination appropriate to the standard of care relating to the patient's condition, including an assessment of physical and psychological function, and an evaluation of underlying or coexisting physical and

psychological diseases or conditions, including anxiety and depression;

3. Make a reasonable effort to obtain and review the patient's medical record;

4. Determine, when treating the patient's pain, if the patient was previously issued a prescription for, used, or was administered a drug or its pharmaceutical equivalent. The practitioner may make this determination by reviewing the patient's medical record, if available, reviewing the patient's prescription monitoring information, or consulting with the patient;

5. (No change in text.)

6. Develop a treatment plan; and

7. Prepare a medical record, which includes the:

i. Medical history;

ii. Findings on examination;

iii. Relevant PMP data;

iv. Efforts made to obtain the patient's medical records;

v. Treatment plan; and

vi. Medications prescribed, dispensed, or administered, including:

Recodify existing i.-iii. as (1)-(3) (No change in text.)

(c) With respect to Schedule II controlled dangerous substances, unless the requirements of this subsection are met or the prescribing of opioids is subject to limitations as set forth at (g) below, a practitioner 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 at (g) below.

1. (No change.)

2. Notwithstanding the 30-day supply limitation, a physician may prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance provided that:

i.-ii. (No change.)

iii. The practitioner determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

iv. The practitioner evaluates the benefits and harms of opioid therapy when treating a patient for pain, and determines that clinically meaningful improvement in pain and function outweigh the risks to patient safety; and

v. (No change in text.)

(d) 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 practitioner 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 treatment plan, including the objectives to be accomplished with the medication, 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.-3. (No change.)

(e) Prior to the commencement of an ongoing course of treatment for chronic pain with a Schedule II controlled dangerous substance or any opioid, the practitioner 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 practitioner 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. Document the understanding of both the practitioner and the patient regarding the patient's treatment plan, taking into account the patient's history since being initiated on opioids, current progress toward objectives in the treatment plan, and modified treatment objectives, as appropriate, and in accordance with the standard of care;

2.-5. (No change.)

(f) When controlled dangerous substances are continuously prescribed for management of chronic pain, the practitioner 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 discuss with the patient the course of treatment and progress toward objectives in the treatment plan and document the results of that review;

2.-3. (No change.)

4. Discontinue (through tapering, if necessary) opioid therapy, in accordance with the standard of care if there is insufficient clinically meaningful improvement in pain and function;

5. (No change in text.)

6. Monitor compliance with the pain management agreement and continue to assess whether the patient's improvement in pain and function outweigh risks to patient safety;

7. Monitor compliance with any recommendations that the patient seek a referral;

8. Discuss with the patient any breaches that reflect that the patient is not taking the drugs as prescribed, is taking illicit drugs, or is taking other prescribed drugs without informing the practitioner, and document within the patient record the plan after that discussion;

9. (No change in text.)

10. 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

11. Refer the patient to a pain management or addiction specialist for independent evaluation or treatment if the patient is not attaining clinically meaningful improvement in pain and function, in accordance with the treatment plan.

(g) A practitioner 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 practitioner shall not issue an initial prescription for an [page=112] 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 practitioner may issue a subsequent prescription for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription provided the following conditions are met:

1. (No change.)

2. After the consultation with the patient and consideration of the treatment plan, the practitioner, 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 and is consistent with the treatment plan;

3.-4. (No change.)

5. When a patient is prescribed a course of opioid treatment that is to last more than 35 days, the practitioner shall discuss with the patient an exit strategy consistent with the standard of care for the discontinuation of opioids in the event they are not providing clinically meaningful improvement in pain or function, and shall modify the treatment plan to include the exit strategy; and

6. The practitioner shall include a note in the record that the exit strategy discussion required at (g)5 above, took place.

(h) (No change.)

(i) Except as provided at (i)1 below, when a practitioner issues a patient a prescription for an opioid drug that is a controlled dangerous substance, the practitioner shall also issue the patient a prescription for an opioid antidote when 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, 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 practitioner shall not be required to issue more than one prescription for an opioid antidote to a patient per year.

2. Nothing at (i)1 above shall be construed to prohibit a practitioner from issuing additional prescriptions for an opioid antidote to a patient upon the patient's request or when the practitioner determines there is a clinical or practical need for the additional prescription.

(j) The requirements for prescribing controlled dangerous substances set forth at (d) through (i) 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.

(k) (No change in text.)

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