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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: April 6, 2020, at 52 N.J.R. 676(a).

Adopted: September 9, 2020, by the State Board of Medical Examiners, Scott E. Metzger, M.D., President.

Filed: December 10, 2020, as R.2021 d.007, **without change.**

Authority: N.J.S.A. 45:9-2 and P.L. 2017, c. 341.

Effective Date: January 19, 2021.

Expiration Date: April 3, 2025.

Summary of Public Comment and Agency Response:

The official comment period ended June 5, 2020. The State Board of Medical Examiners (Board) received a comment from Jennifer G. Velez, Executive Vice President, Community Health, RWJBarnabas Health.

1. COMMENT: The commenter expressed support for the Board's proposed amendments to N.J.A.C. 13:35-7.6 to require prescribers to co-prescribe an opioid antidote under certain circumstances and to implement P.L. 2017, c. 341, amending N.J.S.A. 24:21-15.2. The commenter appreciates the Board seeking to further increase the public availability of naloxone. The commenter stated that combating substance abuse disorder requires a proactive multifaceted approach. The commenter believes that this is even more critical in the midst of the COVID-19 pandemic and noted that job loss, social isolation, and other consequences of COVID-19 are expected to drive a "second curve" of mental health and substance use related harms, potentially resulting in over 2,000 additional deaths of despair--deaths due to drug and alcohol use and suicide--in New Jersey over the next decade. These risks and COVID-19 related barriers to accessing treatment for opioid use disorder, were acknowledged in the Division of Consumer Affairs Administrative Order No. 2020-08, which requires prescribers to co-prescribe an opioid antidote under certain [page=125] circumstances for the duration of the State of Emergency and Public Health Emergency.

The commenter also expressed support for the Board's proposed amendment to N.J.A.C. 13:35-7.6 such that the topics of discussion required upon initial prescription of an opioid drug for acute pain includes information about the highly addictive nature of the drug even when taken as prescribed and used as directed. The commenter stated that it is essential to provide information about the use of opioids.

RESPONSE: The Board thanks the commenter for its support. The Board also notes that, in accordance with N.J.A.C. 13:35-7.6(i), prescribers do not need to co-prescribe an opioid antidote to a patient who is currently actively being treated for cancer, receiving hospice care from a licensed hospice, receiving palliative care, or residing in a long-term care facility. Additionally, prescribers do not need to co-prescribe an opioid antidote when prescribing medication for treatment of substance abuse or opioid dependence, and the requirement does not apply to medications being administered pursuant to medication orders in in-patient facilities.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments are governed by N.J.S.A. 45:9-1 et seq., and 24:21-15.2 and are not subject to any Federal requirements or standards.

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:

. . .

"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 practitioner shall consult with the patient, review prescription monitoring information, and, to the extent it is available to the practitioner, review the patient's medical record.

. . .

(b) When prescribing, dispensing, or administering controlled dangerous substances, a practitioner 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.)

(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 in (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 in (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.-iv. (No change.)

(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 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 practitioner shall reiterate the discussion required in (d) 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.)

(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.-5. (No change.)

(f) When controlled dangerous substances are continuously prescribed for management of chronic pain, the practitioner 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;

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. (No change to text.)

(g)-(j) (No change.)