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PROPOSED RULE

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LAW AND PUBLIC SAFETY

(a)

DIVISION OF CONSUMER AFFAIRS

STATE BOARD OF MEDICAL EXAMINERS

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

Authorized By: State Board of Medical Examiners, Antonia Winstead, Executive Director.

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2022-022.

Submit written comments by April 23, 2022, to:

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or electronically at: http://www.njconsumeraffairs.gov/Proposals/Pages/default.aspx

The agency proposal follows:

Summary

The United States and the State of New Jersey continue be in the midst of an opioid overdose epidemic. To address this ongoing epidemic and prevent addiction from the outset, the State Board of Medical Examiners (Board) proposes to amend N.J.A.C. 13:35-7.6, so that practitioners identify in advance psychological co-morbidities that affect prescribing and overall treatment decisions and assess whether continued opioid therapy is

working to address the patient's treatment needs. The Board is proposing to amend the rules to ensure that practitioners have a clear understanding of the patient's history from the outset, assess a patient's predilection for addiction and develop treatment objectives accordingly, and continually evaluate whether opioid therapy is providing clinically meaningful improvement in pain and function.

In addition, the Board proposes to amend N.J.A.C. 13:35-7.6 to implement P.L. 2021, c. 54, which was enacted on April 19, 2021, and revises the controlled substances law, N.J.S.A. 24:21-15.2 to establish conditions for co-prescribing an opioid antidote. The statutory conditions that trigger the co-prescription differ from those in the Board's existing rules.

The Board proposes to amend N.J.A.C. 13:35-7.6(a) to include a definition of "opioid antidote," consistent with P.L. 2021, c. 54, and "treatment plan." The Board also proposes to amend subsection (b) to specify that the requirements of the subsection apply at the initiation of the prescribing of, or whenever dispensing or administering, controlled dangerous substances. Additionally, the Board proposes to amend paragraph (b)2 to change the required physical examination from one that is appropriate to the practitioner's specialty to one that is appropriate to the standard of care relating to the patient's condition.

The Board also proposes to amend paragraph (b)2 to specify that the required evaluation of underlying or coexisting diseases or conditions include physical and psychological diseases or conditions, including anxiety and depression. Recommendation 2 of the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain, 2016 (CDC Guidelines) supports the idea of screening for psychological co-morbidities, as it advises clinicians to continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. The explanation for the CDC Guidelines recommendation observes that depression, anxiety, and other psychological co-morbidities often co-exist with and can interfere with resolution of pain.

In addition, the Board proposes to add new paragraph (b)3 to require practitioners to make a reasonable effort to obtain, and review, the patient's medical record. Under proposed new paragraph (b)4, when treating the patient's pain, the practitioner must determine 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, or reviewing the patient's prescription monitoring information, or alternatively consulting with the patient.

With the proposed inclusion of a definition of "treatment plan," the Board proposes to delete the description of a treatment plan from recodified paragraph (b)6.

In addition, the Board proposes to modify the requirements for the medical record at recodified paragraph (b)7 to include the efforts made to obtain the patient's record. Additionally, the Board proposes to amend this recodified paragraph to include the medications prescribed, dispensed, or administered, which includes the information currently required at subparagraphs (b)5i, ii, and iii.

For a physician to prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance, proposed new N.J.A.C. 13:35-7.6(c)2iv will require the physician to evaluate the benefits and harms of opioid therapy when treating a patient for pain, and determine that clinically meaningful improvement in pain and function outweigh the risks to patient safety.

The Board proposes to amend subsection (d), concerning when controlled dangerous substances are initially prescribed for acute pain to require the practitioner to also discuss the treatment plan with the patient, including the objectives to be accomplished with the medication.

The Board proposes to amend paragraph (e)1 to replace documenting the practitioner's and patient's understanding of the pain management plan with documenting the practitioner's and patient's understanding of the 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.

The Board proposes to amend subsection (f), concerning when controlled dangerous substances are continuously prescribed for management of chronic pain. The Board proposes to amend paragraph (f)1 to require a discussion with the patient of the course of treatment and progress toward objectives in the treatment plan. Proposed new paragraph (f)4 requires discontinuing (through tapering, if necessary) opioid therapy in accordance with the standard of care, if there is insufficient clinically meaningful improvement in pain and function. Existing paragraph (f)4 is proposed for recodification as (f)5 without change. Recodified paragraph (f)6 is proposed for amendment to require the practitioner to continue to assess whether the patient's improvement in pain and function outweighs risks to patient safety. The requirement to monitor compliance with recommendations that the patient seek a referral is proposed for removal from recodified paragraph (f)6 and relocated at new paragraph (f)7. Similarly, the requirement to discuss with the patient any breaches that reflect that the patient is not taking the drugs as prescribed, or is taking illicit drugs, or taking drugs prescribed by other practitioners or prescribers without informing the health care practitioner, and document within the patient record the plan after that discussion, is proposed for removal from recodified paragraph (f)6 and relocated at new paragraph (f)8.

P.L. 2021, c. 54, provides that when a health care practitioner issues to a patient a prescription for an opioid drug that is a controlled dangerous substance, the prescriber shall additionally issue the patient a prescription for an opioid antidote if any of the following conditions are present: (a) the patient has a history of substance use disorder; (b) the prescription for the opioid drug is for a daily dose of more than 90 morphine milligram equivalents; or (c) the patient holds a current, valid prescription for a benzodiazepine drug that is a Schedule III or Schedule IV controlled dangerous substance. Because P.L. 2021, c. 54 requires a co-prescription in the event any of the triggering conditions is met, and not solely in the context of continuous prescribing for management of chronic pain as provided at N.J.A.C. 13:35-7.6(f)8, the Board proposes to delete paragraph (f)8, and add new subsection (i), discussed more fully below, to implement the co-prescribing requirement.

The Board also proposes to amend recodified paragraph (f)11 to require a referral 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.

In addition, the Board proposes to amend subsection (g) concerning the conditions that must be met before a practitioner issues a subsequent prescription for an opioid drug. The Board proposes to amend paragraph (g)2 to include consideration of the treatment plan and add a requirement that the additional days' supply of the prescribed opioid be consistent with the treatment plan. Proposed new paragraph (g)5 requires that, when a patient is continuously prescribed a 35-day supply, 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 modify the treatment plan, accordingly. The proposed 35-day supply includes the initial prescription for up to a five-days' supply and any continuous subsequent prescriptions. Proposed new paragraph (g)6 requires the practitioner to include a note in the record that the required exit strategy discussion took place.

Proposed new subsection (i) implements P.L. 2021, c. 54, by requiring a health care practitioner who issues a prescription for an opioid drug to also issue a prescription for an opioid antidote when certain conditions are met. The new law requires a health care practitioner to co-prescribe an opioid antidote whenever the practitioner prescribes 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; or the patient holds a current, valid prescription for a benzodiazepine that is a Schedule III or Schedule IV controlled dangerous substance. Consistent with the new law, paragraph (i)1 specifies that a practitioner is not required to issue more than one prescription for an opioid antidote to a patient per year. In addition, paragraph (i)2 provides that the practitioner is not precluded 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.

As the Board has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Board believes that the proposed amendments will have a positive impact on the consumers of New Jersey by reducing the risk of addiction and overdose deaths by ensuring that, from the outset, practitioners have a clear understanding of patients' needs and treatment objectives and that practitioners assess a patient's predilection for addiction and evaluate whether the opioid therapy is clinically meaningful.

Economic Impact

The proposed amendments may increase costs for patients who decide to fill prescriptions for the opioid antidote and will similarly increase costs for insurers. To the extent the proposed amendments improve prescribing practice such that fewer individuals develop an addiction to opioids, fewer individuals overdose, fewer individuals present to the emergency room after an overdose, and fewer individuals seek care for addiction treatment, there may be a positive economic impact on patients, insurers, and hospitals.

Federal Standards Statement

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

Jobs Impact

The Board does not believe that the proposed amendments will result in the creation or the loss of jobs in the State.

Agriculture Industry Impact

The Board does not believe that the proposed amendments will have any impact on the agriculture industry of the State.

Regulatory Flexibility Analysis

Currently, the Board licenses approximately 38,340 physicians, 1,290 podiatrists, 3,820 physician assistants, and 370 certified nurse midwives. If these licensees are considered "small businesses" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., then the following analysis applies.

The proposed amendments will impose new recordkeeping and compliance requirements that are discussed in the Summary above. No additional professional services will be needed to comply with the proposed amendments. The costs of compliance are discussed in the Economic Impact statement above. The proposed amendments should be uniformly applied to all licensed practitioners who are authorized to prescribe drugs in order to ensure the health, safety, and welfare of the general public. Therefore, no additional compliance requirements for any licensed practitioner are provided based upon the size of the business.

Housing Affordability Impact Analysis

The proposed amendments will have no impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the rulemaking would evoke a change in the average costs associated with housing because the proposed amendments concern the prescribing, administering, or dispensing of controlled dangerous substances.

Smart Growth Development Impact Analysis

The proposed amendments will have no impact on smart growth development and there is an extreme unlikelihood that the proposed amendments would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the proposed amendments concern the prescribing, administering, or dispensing of controlled dangerous substances.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Board has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the proposal follows: (additions indicated in boldface thus; deletions indicated in brackets ~~thus~~):

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 ~~administering~~the administration of controlled dangerous substances, a practitioner shall:

1. (No change.)

2. Conduct a physical examination appropriate to the ~~practitioner's specialty~~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;

~~3.~~ 5. (No change in text.)

~~4.~~6. Develop a treatment plan~~, which identifies the objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological 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.~~7. Prepare a medical record, which ~~reflects~~includes the ~~medical~~:

i. Medical history~~, the findings~~;

ii. Findings on examination~~, any relevant~~;

iii. Relevant PMP data~~, and the treatment~~;

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

v. Treatment plan~~, as well as:~~; 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 ~~in~~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 ~~in~~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; ~~and~~

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

~~iv.~~ 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 ~~pain management~~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;

~~4.~~ 5. (No change in text.)

~~5.~~6. 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 other practitioners or prescribers, and document within the patient record the plan after that discussion~~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;

~~6.~~ 9. (No change in text.)

~~7.~~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

~~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.~~11. 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~~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 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.

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

~~(j)~~(k) (No change in text.)