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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 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) A licensee shall issue written prescriptions only on New Jersey Prescription Blanks (NJPB) that have been secured from an approved vendor and which meet the security

requirements of the prescription blanks program set forth in N.J.A.C. 13:45A-27. A licensee's NJPB shall include all information required to appear on the blank pursuant to Division of Consumer Affairs rules, set forth at N.J.A.C. 13:45A-27, including the licensee's National Provider Identifier, if one has been obtained.

- 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 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) 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) 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 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.