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Full text of the proposed amendments follows (additions indicated in bold face **thus**):

SUBCHAPTER 2A. Limited Licenses: Midwifery

13:35-2A.14 Prescriptive authorization

(a) - (h) (No change.)

(i) When prescribing controlled dangerous substances, a CNM shall comply with all of the requirements and limitations as set forth in N.J.A.C. 13:35-7.6 and N.J.A.C. 13:45H.

SUBCHAPTER 2B. Limited Licenses: Physician Assistants

13:35-2B.12 Requirements for issuing prescriptions for medications; special requirements for issuance of CDS

(a) - (b) (No change.)

(c) A physician assistant may order or prescribe controlled dangerous substances (CDS) if:

1. A supervising physician has authorized a physician assistant to order or prescribe Schedule II, III, IV or V controlled dangerous substances in order to:

i. – iv. (No change.)

2. The physician assistant has registered with and obtained authorization to order or prescribe controlled dangerous substances from the appropriate State and Federal agencies**; and**

3. The physician assistant complies with all of the requirements and limitations as set forth in N.J.A.C. 13:35-7.6 and N.J.A.C 13:45H.

(d) - (e) (No change.)

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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 rule, 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 practitioner 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

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the drug or its equivalent. When determining whether a patient was previously issued a prescription for 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.

"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.

"Practitioner" means an individual currently licensed, registered, or otherwise authorized to prescribe drugs in the course of professional practice, to include a physician, a podiatrist, a physician assistant, and a certified nurse midwife, acting within the scope of practice of his or her professional license or certification.

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

1. Take a thorough medical history of the patient which reflects the nature, frequency, and severity of any pain, 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 physical examination appropriate to the practitioner's specialty, including an assessment of physical and psychological function, and an evaluation of underlying or coexisting diseases or conditions;

3. Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to section 8 of P.L.2015, c.74 (C. 45:1-46.1) and consider that information in accordance with N.J.A.C. 13:45A-35;

4. 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. Prepare a medical record which reflects the medical history, 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.

(c) With respect to Schedule II controlled **dangerous** substances, unless the requirements below are met **or the prescribing of opioids is subject to limitations as set forth in subsection (g)**, a practitioner **may** authorize a quantity**, not to** exceed a 30-day supply, **which shall be at the**

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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 subsection (g).

1. Notwithstanding the 30-day supply limitation, a practitioner may prescribe the use of an implantable infusion pump that is utilized to achieve pain management for patients suffering from cancer, intractable pain, or terminal illness. A prescription for such an implantable infusion pump may provide up to a 90-day supply, as long as the physician evaluates and documents the patient's continued need at least every 30 days; and

2. Notwithstanding the 30-day supply limitation, a practitioner 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. Each separate prescription is issued for a legitimate medical purpose by the practitioner acting in the usual course of professional practice;

ii. The practitioner provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription;

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

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iv. The practitioner complies with all other applicable State and Federal laws and regulations.

(d) Prior to issuing the first prescription for a Schedule II controlled dangerous substance for pain or any opioid drug, 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, 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.

i. If the patient is under 18 years of age and is not an emancipated minor, the practitioner shall have the discussion required in section (d) prior to the issuance of each subsequent prescription for any opioid drug which is a Schedule II controlled dangerous substance.

ii. In addition to the requirements of subparagraph (i), the practitioner shall reiterate the discussion required in section (d) prior to issuing the third prescription of the course of treatment for a Schedule II controlled dangerous substance for pain or any opioid drug.

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iii. The practitioner shall include a note in the patient record that the required discussion(s) took place.

(e) At the time of issuance of the third prescription for a Schedule II controlled dangerous substance for pain or any opioid drug, 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 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 practitioner 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 practitioners 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;

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4. Specify the measures the practitioner 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 practitioner has reason to believe that the patient is not complying with the terms of the agreement.

(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 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;**

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4. Access relevant prescription monitoring information as maintained by the Prescription Monitoring Program (PMP) pursuant to section 8 of P.L.2015, c.74 (C. 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 other practitioners or prescribers , and document within the patient record the plan after that discussion;

6. Conduct random urine screens at least once every 12 months;

7. For those patients being prescribed an opioid drug to treat chronic pain, 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.

(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

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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. The practitioner consults (in person, via telephone, or other means of direct communication) with the patient;

2. After the consultation with the patient, the practitioner, in the exercise of 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 practitioner 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 in paragraph 2 above, and:

i. Any subsequent prescription for an additional days' supply shall not exceed a 30-day supply, unless authorized pursuant to (c) above.

(h) When a practitioner issues an initial prescription for an opioid drug for the treatment of acute pain, the practitioner shall so indicate it on the prescription.

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(i) The requirements for prescribing controlled dangerous substances set forth in subsections (d) through (h) above shall not apply to a prescription for a patient who is currently in active treatment for cancer, or receiving hospice care from a licensed hospice, or 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) Nothing in subsection (g) shall be construed to limit a practitioner's professional judgment to authorize a subsequent prescription for an opioid drug in a quantity consistent with subsection (g)4 for the continued treatment of acute pain associated with the condition that necessitated the initial prescription.