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RULE ADOPTIONS

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

Adopted Concurrent Amendments: N.J.A.C. 13:35-2A.14, 2B.12, and 7.6

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: March 20, 2017, at 49 N.J.R. 552(a).

Adopted: April 28, 2017, by Christopher S. Porrino, Attorney General, State of New Jersey and April 25, 2017, by George J. Scott, D.P.M., D.O., President, State Board of Medical Examiners.

Filed: April 28, 2017, as R.2017 d.109, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:1-17.b and 45:9-2

Effective Date: April 28, 2017, Concurrent Adopted Amendments;
June 5, 2017, Changes Upon Adoption.

Expiration Date: May 3, 2018.

Summary of Public Comments and Agency Responses:

The official comment period ended April 19, 2017. The Attorney General and the State Board of Medical Examiners (Board) received comments from the following:

1. Brian Culp, M.D., Princeton Orthopaedic Associates, Orthopaedic Surgeon, Adult Reconstruction and Joint Replacement;
2. Mischael Azam, Esq., on behalf of the Medical Society of New Jersey; The NJ Academy of Family Physicians; The NJ Society of Plastic Surgeons; The NJ American Academy of Emergency Physicians; the NJ Association of Osteopathic Physicians and Surgeons; the NJ Society of Interventional Pain Physicians; the American Academy of Pediatrics-NJ Chapter; the New Jersey Orthopaedic Society; the New Jersey Society of Physical Medicine & Rehabilitation; the New Jersey State Society of Anesthesiologists; and the New Jersey Chapter, American College of Surgeons.
3. Robert Carullo, Executive Director, SMART (Strengthening the Mid-Atlantic Region for Tomorrow) Congressional Initiative;
4. Joseph N. Ranieri, D.O., Dipomate-ABAM, Seabrook House Medical Director, President,

NJSAM;

5. Debbie Burrell, Board Member & Healthcare Chair, Strengthening the Mid-Atlantic Region for Tomorrow, and President, Burrell International Group, LLC;

6. Mandi S. Love, Esq., RN-BC, CLNC;

7. Michael W. Shore, M.D., DLFAPA, DFASAM;

8. Karen Etherington;

9. Allyson Hurley; and

10. Rebecca Levy, Esq., General Counsel, Summit Medical Group.

1. COMMENT: One commenter, an orthopedic surgeon, noted that there are a number of procedures that have acute post-surgical pain that are expected to require Schedule II medications for greater than five days. The commenter also noted that many patients who recently undergo surgery for joint replacement, for example, are not able to leave the home and get to the office for several weeks, and require home nursing, and other home therapies. The commenter expressed concern that the proposed amendments do not account for "acute surgical pain" and will put these patients at risk of suffering, and worse outcomes. The commenter requested advice for this circumstance and that this be factored into the consideration for the rule proposal. One commenter asked how the proposed regulations will impact the ability of a patient to obtain medication following a complete double-knee replacement, when the patient is in the need of pain medication. Another commenter expressed concern about the ability of patients who are suffering from pain to obtain pain medication.

RESPONSE: The Attorney General and Board note that the rule is not to be construed to limit a licensee's professional judgment to issue subsequent prescriptions for an opioid drug for the continued treatment of acute pain associated with the condition that necessitated the initial prescription. Instead, the rule is intended to infuse into the licensee/patient relationship a need for consultation after the expected course of recovery and prior to issuing additional prescriptions. Practitioners are encouraged to prescribe a supply of opioids that are appropriate to the patient's treatment needs at a particular stage of recovery and does not present an undue risk of abuse, addiction, or diversion.

2. COMMENT: One commenter suggested that, as it is used for consent and pain management agreement requirements, the "third prescription" be defined. The commenter noted that there is great confusion, including the difference between the treatment of acute and chronic pain, and the requirements triggered by the third prescription. The commenter noted, for example, that after a surgery a physician may prescribe an opioid medication for five days, then a second five-day supply, and then another five days of medication. The commenter further stated that the physician will not maintain a relationship with the patient after the post-operative treatment, so she should not be required to obtain consent upon writing the third five-day prescription (after just 10 days). The commenter also stated that a prescriber will not know precisely how many prescriptions for an opioid for pain a patient previously received, even if checking the Prescription Monitoring Program (PMP). The commenter believes that this will cause improper counting of prescriptions. The commenter provided a second example: Patient X received two five-day prescriptions for opioids in January after dental surgery. When Patient X undergoes back surgery later in the year, the opioid prescription written by the back surgeon could be considered a "third prescription,"

triggering the prescriber to "reiterate" consent as if the prescription was part of a series and the care was ongoing, even if the surgeon never saw the patient before or will see the patient after post-operative care. The commenter suggested that the following definition be added to N.J.A.C. 13:35-7.6(a):

"Third prescription" means the third prescription for a 30 day supply of medication issued by the same prescriber or practice in the [page=1434] past year to treat the same acute or chronic pain condition, not including an initial prescription.

RESPONSE: The Attorney General and the Board agree that "third prescription" is a term that needs to be defined, but decline to define it as the commenter suggests. The Board will address this in a future rulemaking.

3. COMMENT: One commenter recommended that N.J.A.C. 13:35-7.6(d) be amended, so that "first prescription" in the first sentence is changed to "initial prescription," using the defined term.

RESPONSE: The Attorney General and Board agree that the use of "first prescription" is confusing. To avoid this confusion and to be consistent with using a defined term, upon adoption, the Attorney General and Board will change N.J.A.C. 13:35-7.6(d) to replace "first prescription" with "initial prescription."

4. COMMENT: One commenter noted that the current statute and regulation allow for 90 days of an opioid prescription (the "30x3" rule) (see N.J.S.A. 45:9-22.19(b) and 13:35-7.6(c) and (d) and N.J.A.C. 13:45A-35.9). The commenter stated, however, that P.L. 2017, c. 28 inadvertently shortens this period to 60 days/two months by imposing requirements that force a patient visit before a third prescription is issued, rather than requiring those actions at the quarterly or three month mark, when the fourth prescription is issued. The commenter further stated that a prescriber must obtain consent and enter into a pain management agreement prior to (or at the time of) the third prescription, forcing a conflict between current law and the new law. The commenter recommends, in order to allow prescribers to "issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance," while reducing potential for medication misuse, the inclusion of the following language as N.J.A.C. 13:35-7.6(d)iv:

"The practitioner may comply with the requirement (N.J.A.C. 13:35-7.6(d)ii) through in-person, telephonic, or electronic communication, including online patient portals."

RESPONSE: The Attorney General and the Board decline to change N.J.A.C. 13:35-7.6(d) to include the language that the commenter suggested because P.L. 2017, c. 8 (establishing the discussion requirements with minors before issuing prescriptions for Schedule II opioids) and P.L. 2017, c. 28 (establishing the discussion requirements for prescriptions for Schedule II controlled dangerous substances and all other opioid drugs) and N.J.A.C. 13:35-7.6(d) do not mandate that the required discussion be conducted in-person with the patient or the patient's parent or guardian and, therefore, the suggested change is unnecessary.

5. COMMENT: One commenter sought clarification concerning the discussion requirements in recognition of scenarios in which prescribers cannot obtain consent, including post-anesthesia recovery. The commenter noted that such scenarios are recognized in N.J.A.C. 13:45A-35.9. The commenter recommends including the following language as N.J.A.C. 13:35-7.6(d)v:

"The requirements of this subsection shall not apply to a practitioner who is prescribing an

initial prescription immediately after a patient has undergone an operation, invasive procedure that requires anesthesia, or treatment for acute trauma."

RESPONSE: The Attorney General and Board note that the discussion requirements of N.J.A.C. 13:35-7.6 are triggered when issuing a prescription, and not when administering a Schedule II controlled dangerous substance or opioid medication. A practitioner who anticipates post-surgery issuing a prescription that would trigger the discussion requirements should have the discussion with the patient, or patient's parent or guardian before the surgical procedure.

6. COMMENT: One commenter noted that pursuant to Section 11 of P.L. 2017, c. 28, pain management agreements are only required for the treatment of chronic pain. The commenter, therefore, requests that N.J.A.C. 13:35-7.6(e), which sets forth the requirement for the agreement, be amended to be consistent with the statute as follows:

"At the time of issuance of the third prescription for a Schedule II controlled dangerous substance for chronic pain or any opioid drug, the practitioner shall enter into a pain management agreement with the patient."

RESPONSE: Due to the opioid crisis, the Attorney General and Board believe it is necessary to provide enhanced protection for all patients. The Attorney General and Board, however, recognize that the term "third prescription," which triggers the requirement to enter into a pain management agreement, needs to be defined. The Board will address this in a future rulemaking.

7. COMMENT: One commenter noted that, in practice, many prescribers require pain management agreements before the third prescription of an opioid for the treatment of chronic pain is issued. The commenter also stated that many practices require such agreements before opioid regimens even begin. The commenter further stated that P.L. 2017, c. 28 appears to be inconsistent by defining the term as something executed "prior to the commencement of treatment for chronic pain" in section 11.g., but then also requiring in section 11.e., that the agreement be executed "at the time of the issuance of the third prescription for a prescription opioid drug." The commenter recommended addressing this inconsistency and encouraging the practice of executing pain management agreements consistent with the defined term by adding the following language after the first sentence in N.J.A.C. 13:35-7.6(e):

"If a pain management agreement is executed before the third prescription, no additional agreement is needed."

RESPONSE: The Attorney General and Board agree that if a practitioner has entered into a pain management agreement with a patient prior to the issuance of the third prescription it is not necessary to enter into an additional pain management agreement. Upon adoption, the Attorney General and the Board will change N.J.A.C. 13:35-7.6(e) to include clarifying language. Additional public notice of this change is not required because it does not change the effect of this rule nor does it increase the burden on the practitioners.

8. COMMENT: One commenter recommended amending proposed N.J.A.C. 13:35-7.6(f)1 to delete "and document the results of that review." The commenter noted that paragraph (f)1 requires documentation of quarterly reviews of a patient's treatment protocols. The commenter further stated that, given that consent must be obtained and the PMP must be checked at these same intervals, the commenter requests that the requirement for documentation be removed because it goes beyond the statutes to create an administrative

burden. The commenter further noted that consent must already be documented in the record, which already necessitates documentation of a review.

RESPONSE: The Attorney General and Board decline to delete the documentation requirement because it is required under P.L. 2017, c. 28 and it is an element of good practice.

9. COMMENT: One commenter noted that N.J.A.C. 13:35-7.6(f)3 requires prescribers to "document, with specificity, the efforts undertaken" 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. The commenter requested that this requirement for documentation be removed because the pain management agreement covers these concerns. The commenter further noted that the new law and the proposed regulations require great changes in physician practices and hope that requirements beyond the statute are not included. The commenter recommended amending proposed N.J.A.C. 13:35-7.6(f)3 to delete "and document with specificity, the efforts undertaken."

RESPONSE: The Attorney General and Board decline to delete the documentation requirement because it is required under P.L. 2017, c. 28 and it is an element of good practice. The current opioid crisis necessitates that practitioners be more mindful of the risks and lack of efficacy of long-term opioid prescribing, and the need to try alternatives.

10. COMMENT: One commenter noted that proposed N.J.A.C. 13:35-7.6(f)7 includes redundant language by starting with "for those patients being prescribed an opioid drug to treat chronic pain" because the entire section concerns controlled dangerous substances prescribed for chronic pain. The commenter, therefore, recommended that this clause be deleted with capitalization corrected.

RESPONSE: Upon adoption, the Attorney General and the Board will change N.J.A.C. 13:35-7.6(f)7 to remove the redundant language. [page=1435] Additional public notice of this change is not required because it does not change the effect of this rule.

11. COMMENT: One commenter requested that proposed N.J.A.C. 13:35-7.6(f)6 be softened because the lack of insurance coverage for urine drug testing may expose patients to increased costs. The commenter noted that, thorough urinalysis that tests for positives and negatives is hard to obtain. The commenter also noted that urine tests indicate only that a drug is present, not if the patient is taking the right amount of the medication. The commenter stated that studies have shown that urine tests often give false results for drugs like marijuana, oxycodone, and methadone. The commenter further stated that urine testing may not be the best test, with saliva or blood testing emerging as valid alternatives. The commenter recommended amending N.J.A.C. 13:35-7.6(f)6 to delete "conduct random urine screens at least once every 12 months" and to include "Monitor the patient's compliance, including but not limited to, random specimen screens and pill counts."

RESPONSE: The Attorney General and Board decline to amend N.J.A.C. 13:35-7.6(f)6 as the commenter suggested because they believe the use of random urine screens is an additional mechanism prescribers should use to assure that patients are complying with their prescribed treatment regimen. In addition, urine screenings enhance the way prescribers can be informed about the best medication choices for their patients and help to assure that diversion is not occurring.

12. COMMENT: One commenter expressed concern about the requirement for prescribers to make an indication on a prescription that it is an initial prescription. The commenter noted that she is unclear about the purpose of this requirement and requests the removal of N.J.A.C. 13:35-7.6(h).

RESPONSE: The Attorney General and the Board decline to delete proposed N.J.A.C. 13:35-7.6(h). P.L. 2017, c. 28 establishes how insurance plans will charge the co-payment, coinsurance, or deductible for an initial prescription of an opioid drug prescribed in accordance with the law. To determine which prescriptions are subject to the law's requirements and to ensure patients are properly charged these costs, the prescription for an opioid drug must reflect when it is for an initial prescription for the treatment of acute pain.

13. COMMENT: Four commenters recommended including a requirement that prescribers co-prescribe naloxone, an opioid overdose antidote. The commenters noted that a key lifesaving part of the Centers for Disease Control and Prevention (CDC) guidelines includes co-prescribing naloxone or opioid antagonists for at-risk patients. The commenters stated that co-prescribing naloxone has increasingly gained support across a broad range of stakeholders, including Federal agencies, medical professional associations, and patient advocates as an effective way of increasing access to naloxone and tackling the opioid addiction crisis. The commenters also noted that, in 2016, both the American Medical Association and the CDC issued guidelines that called upon physicians to offer naloxone when factors that increase risk for opioid overdose, such as a history of overdose, substance use disorder, high-dose opioids, or opioids prescribed concurrently with benzodiazepines, are present. Another commenter recommended that the proposed regulations include the ability of a patient or family member to obtain the opiate overdose reversal medication naloxone (Narcan) at any pharmacy without a prescription. This commenter noted that many states have enacted this regulation, including Pennsylvania. The commenter also noted that this can and has been a lifesaving medication approach for patients with opiate use disorders, including prescription opiates and/or heroin, and also for legitimately prescribed opiate pain medications when patients accidentally take an excess and overdose. The commenter believes that patients and their friends and relatives should have this readily available, as it is increasingly available in schools and other venues. The commenter also believes that the legislation should include language that the patient's insurance carrier would pick up the cost of this medication if a person obtains it directly from a pharmacy.

RESPONSE: The Attorney General and Board agree that opioid overdose antidotes are a meaningful way to save lives. The Overdose Prevention Act, N.J.S.A. 24:6J-1 et seq., governs the prescribing and dispensing of an opioid antidote, including naloxone hydrochloride. Under this act, an opioid antidote may be dispensed pursuant to a patient-specific prescription or via a standing order issued in accordance with the law. N.J.A.C. 13:35-7.6(f)7 specifies that for those patients being prescribed an opioid drug to treat chronic pain, the practitioner shall discuss the availability of an opioid antidote. In addition, the Board anticipates posting on its website frequently asked questions that will encourage a discussion about opioid antidotes. The Attorney General and the Board believe that mandating the co-prescribing of an opioid antidote for at-risk patients and requiring insurance coverage for the cost of this medication are beyond the scope of this rulemaking.

14. COMMENT: One commenter stated that it is supportive of the Governor's goals of curbing the opioid crisis facing the residents of our State. The commenter, however, also believes that the "one size fits all" approach of limiting all initial prescriptions to five days and implementing stringent and burdensome requirements on prescribers is not necessary to accomplish the intended outcome.

RESPONSE: The Attorney General and the Board thank the commenter for its support. P.L. 2017, c. 28 does not establish different prescribing requirements and limitations based upon a practitioner's specialty. Consistent with the statute and, to ensure the health, safety, and welfare of the general public, the Attorney General and Board believe that the adopted amendments should be uniformly applied to all licensed practitioners.

15. COMMENT: One commenter noted that providers currently routinely take medical histories prior to prescribing controlled dangerous substances or opioids to their patients. The commenter believes that implementing regulations for all providers (regardless of specialty) that specifically delineate what must be contained in the medical history is not necessary. The commenter expressed concern that requirement for all physicians to address (and thus document) the patient's experience specifically related to non-opioid medication and non-pharmacological pain management approaches, access information contained in the PMP, and develop a treatment plan particular to pain, mandate that all physicians engage in the practice of pain management. The commenter noted that the practice of pain management is a complicated specialty requiring years of residency and fellowship training, and would necessitate that certain physicians practice beyond the scope of their particular medical specialty. In addition, the commenter expressed concern that the specific regulations concerning the practice of medicine will lead plaintiff's attorneys to create a new cause of "addiction" medical malpractice actions with respect to providers who may unintentionally fail to adhere to a particular requirement contained within the extensive new regulations.

RESPONSE: P.L. 2017, c. 28 establish the requirements set forth at N.J.A.C. 13:35-7.6(b)1 (patient's experience specifically related to non-opioid medication and non-pharmacological pain management approaches), (b)3 (access information contained in the PMP), and (b)4 (develop a treatment plan particular to pain). The Attorney General and Board believe that, to the extent practitioners who are not pain management specialists are prescribing pain medications, these adopted amendments establish standards to guide them in their practice, including referring patients to a pain management or addiction specialist for independent evaluation or treatment when treatment objectives are not being met.

16. COMMENT: One commenter noted that pain management specialists routinely utilize opioid medication agreements similar to those referenced in the regulations. The commenter stated, however, that the mandate that all patients enter into such agreements at the time of issuance of the third prescription is unduly burdensome and not complementary to every patient's circumstances. The commenter provided the following example: a patient may have had three different surgeries (sometimes by three different physicians/specialists), within the course of one year, each of which necessitates appropriate opioids for post-surgical pain. The commenter believes that, in this situation, expecting the individual patient to enter into a pain management agreement outlining random specimen screens and pill counts, etc., would not be clinically warranted. The commenter does not believe that this was the intent of the new subsection and is seeking clarification.

RESPONSE: As previously noted, the Attorney General and Board agree that the "third prescription," which triggers the requirement to enter into a pain management agreement, needs to be defined and will be addressed in a future rulemaking.

[page=1436] 17. COMMENT: One commenter expressed concern that the need to check the PMP to determine whether a prescription is indeed an "initial prescription" imposes significant operational difficulties. The commenter noted, for example, that providers

routinely cover other providers over weekends and oftentimes a physician is called to prescribe for another physician's patient post-surgery. The commenter stated that, in such situations, expecting the covering, "on-call" provider to access the PMP (currently not available as a mobile application) to check whether a prescription is an "initial prescription" is not practical and imposing this requirement, without exceptions, will have negative effects on patients who may truly be suffering from pain.

RESPONSE: P.L. 2017, c. 28 establishes the requirement for the practitioner to consult with the patient, and review the patient's medical record and prescription monitoring information when determining whether a patient was previously issued a prescription for a drug or its pharmaceutical equivalent. Practitioners may access the PMP through a mobile application, which is available for download for Apple iOS, Android, and Windows phone users. However, as a result of changes in the PMP vendor software, there have been periods of time when the mobile application has been temporarily unavailable.

Summary of Agency-Initiated Changes:

The Attorney General and the Board are changing N.J.A.C. 13:35-7.6(d)2 to remove reference to subparagraph (i), which was an artifact from a prior draft of the emergency adoption. This change does not require any additional public notice because it does not change the effect of this rule.

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. To the extent that the CDC Guideline may be viewed as establishing and setting forth Federal standards and requirements for the prescribing and dispensing of opioid drugs, the adopted amendments are consistent with these standards.

Full text of the adopted amendments follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[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 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.-iii. (No change.)

iv. Initiate an order or prescription for a controlled dangerous substance as part of a treatment plan for a patient with a terminal illness, which for the purposes of this subparagraph means a medical condition that results in a patient's life expectancy being 12 months or less as determined by the supervising physician;

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 13:45H.

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

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:

"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 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 (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 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 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 [page=1437] frequency of dosage. The prescribing of opioids in any schedule is subject to limitations as set forth in (g) below.

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.-iv. (No change.)

(d) Prior to issuing *[the first]* ***an initial*** 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.

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

2. *[In addition to the requirements of (i) below, the]* ***The*** practitioner shall reiterate the discussion required in (d) 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 practitioner shall include a note in the patient record that the required discussion(s) took place.

(e) 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 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;

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;

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 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]*
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 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 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 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 under (g)² above and 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.

(i) The requirements for prescribing controlled dangerous substances set forth in (d) through (h) 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) Nothing in (g) above shall be construed to limit a practitioner's professional judgment to authorize a subsequent prescription for an opioid drug in a quantity consistent with (g)⁴ above for the continued treatment of acute pain associated with the condition that necessitated the initial prescription.