FREQUENTLY ASKED QUESTIONS For Practitioners Licensed by the Board of Medical Examiners.

To better understand how to comply with statutory and regulatory limitations on prescribing opioids for acute and chronic pain, the Board offers the following guidance.

1. Q: What is the 5 day rule for initial opioid prescriptions for the treatment of acute pain?

A: A prescriber may not issue an initial opioid prescription for acute pain in a quantity exceeding a five day supply. In addition, the initial prescription shall be for the lowest effective dose of an immediate release opioid drug.

2. *Q*: Who is subject to the rule?

A: This rule applies to licensed physicians, podiatrists, physician assistants, and certified nurse midwives, all of whom are authorized to prescribe drugs in the course of professional practice. Advanced practice nurses, dentists, and optometrists are also covered by the law, but regulated by other licensing boards.

3. Q: What is acute pain?

A: "Acute pain" is defined as "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." Post-operative pain is considered acute. "Acute pain" is distinguishable from 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.

4. Q: What is meant by the "initial prescription?"

A: An "initial prescription" means a prescription issued to a patient who:

Has never been issued a prescription for the drug or its pharmaceutical equivalent; or was previously issued a prescription for, or used or was administered the drug or its pharmaceutical equivalent, but not within one year of the date of the current prescription.

5. Q: If someone is administered an opioid pre- or peri-operatively for surgery, is a prescription for post-surgical pain limited to 5 days?

A: No. Since the administration of an opioid pre- or peri-operatively occurred within one year of the current opioid prescription for post-surgical pain, the current prescription is not deemed an "initial" prescription, and therefore, is not subject to the five day rule. In this scenario, the post-surgical pain prescription is a subsequent prescription. See FAQ 11, to read about practitioner's responsibilities when issuing subsequent prescriptions for acute pain.

6. Q: How do I determine whether a patient was previously issued a prescription for, or used, or was administered for a drug or its pharmaceutical equivalent?

A: You should elicit information from the patient concerning his or her medication history, review prescription monitoring information available in the New Jersey Prescription Monitoring Program (NJPMP), and, to the extent available, review the patient's medical record to determine whether the patient has been prescribed, has been administered or

has used the medication or its pharmaceutical equivalent in the last year. To the extent feasible, you may want to reach out to prior-treating prescribers or an identified pharmacy to confirm prior prescribing. Remember that the NJPMP will not include prescription information if prescriptions were filled in another state, although you may be able to access PMPs in other states. Nor will it include medications that were provided in a hospital or ambulatory care facility. Because the patient may have an immediate need, it is not necessary for the practitioner to await the production of a medical record from prior-treating healthcare professionals, but those undertaking to provide ongoing care to the patient should make efforts to incorporate relevant treatment records into their medical record and coordinate with other healthcare professionals who had treated the patient previously or are treating the patient concurrently.

7. Q: What determines the five-day supply?

A: The five-day supply is determined by the directed dosage and frequency of the dosage that you authorize.

8. Q: What is meant by the lowest effective dose?

A: When opioids are started, practitioners should prescribe the lowest effective dosage of immediate release opioids, below 50 MME's per day, and prescribe no more than is needed for the expected duration of pain severe enough to require opioids, especially when prescribing to opioid naive patients. The CDC Guidelines define (MME)/day as the amount of morphine an opioid dose is equal to when prescribed. It is used as a gauge of the abuse and overdose potential of the amount of opioid that is being given at a particular time. Although neither the rule nor the statute reference MME, practitioners may find it helpful in assessing the dosages given, particularly when the patient may be taking more than one opioid.

MME calculations are automatically performed and integrated into a patient's report on the NJPMP. The system displays corresponding MME information for each prescription, as well as a summary of all MME's that patient currently has, based upon the day supply of all prescriptions that are in date.

9. Q: What are immediate-release opioids?

A: Immediate-release opioids are faster acting medications with a shorter duration of pain relieving action.

10. Q: Do I need to indicate on the prescription whether it is an initial prescription?

A: Yes. When issuing an initial prescription for acute pain, you are required to note that on the prescription.

11. Q: Can I issue subsequent prescriptions for the treatment of acute pain?

A: Yes. No less than four days after issuing the initial prescription, and after consulting with the patient, you may issue subsequent opioid prescription(s) for continued treatment of acute pain. That consultation need not be an in-person visit and can be accomplished via a telephone call. The consultation, however, must be with you or a covering prescriber, not office staff. In determining whether to issue another prescription, the prescriber, in the exercise of his or her professional judgment, is obligated to consider and document the

following factors in the patient record:

- (1.) The rationale for the additional "days' supply" of the prescribed opioid drugs, why it is necessary and appropriate to the patient's treatment needs; and,
- (2.) That it does not present an undue risk of abuse, addiction, or diversion.

12. Q: Are there limits on the days' supply for subsequent prescriptions?

A: Other than for initial prescriptions for acute pain, a practitioner may authorize a quantity of Schedule II CDS at the lowest effective dose not to exceed a 30-day supply. The maximum allowable "days' supply" for the first two prescriptions, then, would be a 35-day supply. However, a practitioner should always limit the quantity to the "days' supply" that he or she considers necessary to meet the patient's treatment needs, providing no more than is reasonably expected to be needed at that stage of recovery.

13. Q: What if I expect to be unavailable on the day the patient's supply will run out because I will not be on call?

A: There may be some circumstances, for example, after major surgery or major traumatic injuries, including long bone fractures and severe burns, where the practitioner should plan ahead and make arrangements to consult with the patient on the fourth or fifth day following the initial prescription to assure that the patient has a sufficient supply of medication to meet his or her specific needs. If the prescriber issuing the initial prescription knows that he or she will be unavailable on the fourth or fifth day, he or she may deem it appropriate to alert a covering prescriber that he/she may need to consult with the patient and prescribe an additional days' supply, in order to avoid a disruption in treatment.

14. Q: How will I be able to get the second prescription to the patient so that he or she can fill the prescription at the pharmacy?

A: If you and the patient's pharmacy are able to engage in e-prescribing, the patient will not have to physically obtain the prescription from you. The patient or someone authorized by the patient, of course, will still need to pick up the medication, but the patient will be relieved of the need to physically obtain the prescription. If you or the pharmacy do not have the ability to engage in e-prescribing, and after the requisite consultation, you conclude that the patient's needs can be met by a medication that is classified as a Schedule III controlled substance, you can call in that prescription. If you conclude that the patient has an emergency need for a Schedule II controlled substance, you can call in a 72-hour emergency supply, for which the pharmacist will generate a prescription with all the pertinent information, except your signature. You will need to follow-up with a written prescription within seven days.

15. Q: Are there patients to whom the 5 day rule does NOT apply?

A: Yes. The five-day rule, does not apply to prescriptions for patients in active treatment for cancer, receiving hospice care from a licensed hospice, receiving palliative care, residents in a long term care facility or to any medications prescribed for use in the treatment of substance abuse or opioid dependence. While the statute does not require a discussion of risks of opioids with respect to patients being actively treated for cancer, or in a licensed hospice, or long term care facility, or receiving palliative care, or treatment for substance abuse, the general standard of care should include a discussion of treatment goals and the risks and benefits of therapeutic options.

16. Q: What is "palliative care?"

A: "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.

17. Q: What am I required to discuss with my patient when prescribing a Schedule II controlled substance or any opioid drug?

- A: Prior to issuing a prescription for Schedule II CDS or any opioid drug for acute pain, and prior to issuing such a prescription at the outset of a course of treatment for chronic pain, you must discuss the following:
 - (1.) The reasons why the medication is being prescribed;
 - (2.) The possible alternative treatments; and
 - (3.) The risks associated with the medication.

Patients, adults and minors, should be made aware of all of the risks and benefits of treatment with Schedule II controlled substances or any opioids for acute or chronic pain.

18. Q: Is there anything else I need to discuss with my patients specifically regarding opioid drugs?

- A: Yes, with respect to opioid drugs, you must also discuss at least the following:
 - (1.) The risks of developing addiction, physical or psychological dependence, and overdose associated with opioid drugs;
 - (2.) The danger of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants; and
 - (3.) The requirements for proper storage and disposal.

19. Q: What are the side effects of opioid treatment and withdrawal that I should discuss with the patient at the outset of treatment?

A: You should discuss the possible side effects that the patient may experience to include: nausea, vomiting, constipation, dry mouth, fluid retention, weight gain, weight loss, suppression of the immune system, suppression of thyroid function, suppression of menstrual cycle, suppression of male hormone, sleeping abnormalities, sweating, edema sedation, confusion, depression, itching, and allergic reaction. If addiction or physical dependence develops and the patient stops taking opioids, withdrawal symptoms may include abdominal and muscle cramps, irritability, nausea, vomiting, sweating, body aches, runny nose, yawning, anxiety, and sleep problems. If the patient is pregnant or becomes pregnant while taking opioids, the baby may be physically dependent on the opioids and withdrawal can be life threatening to the baby.

20. Q: With whom do I have these discussions if my patient is a minor?

A: If the patient is under 18 years of age and is not an emancipated minor, you are required

to have these discussions with the patient's parent or guardian. However, given the risks of abuse and overdose associated with opioid treatment, you should consider whether the minor should be included in the discussion, depending on his or her age and level of maturity. If the patient is an emancipated minor, you should have the conversation with the minor.

21. Q: How frequently must I have these discussions if my patient is a minor?

A: You need to have a discussion with the patient's parent or guardian or emancipated minor concerning the risks of opioid treatment prior to the issuance of EVERY prescription for any opioid that is a Schedule II CDS.

22. Q: Once I have these required discussions with my patients, is there a documentation requirement?

A: Yes, you must include a note in the patient record documenting that the discussions took place.

23. Q: Can I just give my patient a handout with information about opioids?

A: No. Although you may give your patient a handout as a supplement to the discussion, you must discuss the risks and benefits of opioid therapy. Good medical practice, and the Board's prior rule, always have required practitioners to thoroughly assess patient needs before prescribing controlled substances. The law now requires explicit discussion in advance of, and during the course of treatment, as well as ongoing monitoring, including the mandatory use of pain management agreements when treating chronic pain (see below).

24. Q: Does the new rule set forth the general steps I need to take when I initiate the prescribing, dispensing, or administering of controlled substances?

- A: Yes, whenever you initiate the prescribing of a controlled substance -- any controlled substance -- for whatever purpose, whether for acute or chronic pain, anxiety or ADHD, you must perform 5 mandatory steps.
 - **STEP 1:** Take a thorough medical history, including the patient's history of substance use or abuse, and, if the presenting complaint involves pain, the history should also address:
 - The nature, frequency, and severity of any pain; and
 - The patient's experience with non-opioid medication and nonpharmacological pain management approaches.
 - STEP 2: Conduct a physical examination appropriate to your specialty, to include an assessment of physical and psychological function, and an evaluation of underlying or coexisting diseases or conditions. As this section of the rule applies to all controlled substances, including those prescribed for conditions other than pain, it is recognized that the type of examination conducted by physicians in certain specialties, like evaluations of psychiatric disorders by psychiatrists, may differ markedly from those undertaken by internists.

- STEP 3: Check the information regarding your patient on the NJPMP and consider that Information when prescribing controlled substances for acute or chronic pain.

 N.J.S.A. 45:1-46.1, the NJPMP statute, requires prescribers to access NJPMP information in the following instances:
 - a) The first time he/she prescribes a Schedule II CDS or ANY opioid to a new patient for acute or chronic pain;
 - b) The first time a he/she prescribes a benzodiazepine drug that is a Schedule III or IV CDS;
 - c) If he/she has a reasonable belief that the person may be seeking a CDS for any purpose other than the treatment of an existing medical condition such as, for purposes of misuse, abuse or diversion, when prescribing for the first time a non-opioid drug other than a benzodiazepine drug that is a Schedule III or IV CDS;
 - d) On a quarterly basis during the period of time the patient continues to receive a Schedule II CDS or any opioid drug, or a Schedule III or IV benzodiazepine drug;
- STEP 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. With respect to patients presenting with pain, you should focus on determining the cause of the patient's pain and identify further diagnostic evaluations to be undertaken and any other treatments planned.
- **STEP 5:** Prepare a detailed medical record which includes the following information:
 - The patient's medical history;
 - Your findings on examination;
 - Any relevant NJPMP data;
 - Your recommended treatment plan;
 - The complete name of the controlled substance;
 - The dosage, strength and quantity of the controlled substance; and
 - The instructions as to frequency of use.
- 25. Q: When I prescribe a Schedule II CDS or any opioid for acute or chronic pain to a patient in the emergency department of a general hospital, am I required to access the NJPMP?
 - A: Yes, every time a practitioner prescribes a Schedule II CDS for acute or chronic pain to a patient receiving care or treatment in the emergency department of a general hospital, he/she is required to access the NJPMP.

26. Q: What is chronic pain?

A: "Chronic pain" means pain that persists or recurs for more than three months.

27. Q. If I am continuing to prescribe Schedule II CDS or any opioid for chronic pain, do I have to go through the five steps described above every time I issue a prescription?

A: No, your ongoing treatment would not require you to conduct as comprehensive of a history or examination of your patient with chronic pain on every visit, but you should assess the ongoing needs of the patient and whether your treatment goals are being met.

28. Q: How does the 30-day supply limitation work in the context of chronic pain patients?

- A: As with the prior Board rule, a practitioner may issue up to three separate prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance provided that:
 - (1.) Each separate prescription is issued for a legitimate medical purpose by the practitioner acting in the usual course of professional practice;
 - (2.) 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;
 - (3.) The practitioner determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and
 - (4.) The practitioner complies with all other applicable State and federal laws and regulations.

There is also an exception for the prescription 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.

29. Q: What am I required to do when prescribing CDS or any opioid for chronic pain?

A: You should:

- (1.) Review, at a minimum of every 3 months, the treatment plan, any new information about the etiology of the patient's pain, the patient's progress and whether treatment goals are being met.
- (2.) Assess the patient prior to issuing each prescription to determine whether the patient is experiencing any problems such as physical or psychological dependence.
- (3.) Make periodic, reasonable efforts, unless clinically contraindicated, to either stop the use of the CDS, taper its dosage or try other medications or alternative treatment modalities. These steps should be taken in an effort to reduce the potential for

abuse or dependence. For guidance to assist you in identifying techniques to taper use, attempt alternative treatments or make referrals, see the following:

- www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf
- <u>www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm</u>
- <u>www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Pain Opioid Taper Tool IB 10 939 P96820.pdf.</u>
- (4.) Access NJ PMP and consider the NJ PMP information in your treatment of the patient.
- (5.) Have your patient enter into a pain management agreement and monitor your patient's compliance with the agreement and discuss any breaches that reflect that the patient is not taking the prescribed medications as instructed or is taking other drugs illicit or prescribed by other practitioners, noting such discussion in the medical record.
- (6.) Conduct random urine screens at least once every 12 months.
- (7.) Advise your patients, or the patient's parent or guardian, of the availability of an opioid antidote if you have prescribed them an opioid drug to treat chronic pain. Consider prescribing naloxone concurrently and advising the patient or a family member to obtain additional information about naloxone.

 See: www.ama-assn.org/delivering-care/opioids/naloxone-5-tips-talking-patients-families.
- (8.) Refer your patient to a pain management or addiction specialist for independent treatment and evaluation or treatment if you deem necessary in order to achieve treatment objectives.
- (9.) Carefully document, with specificity, all of the steps outlined above, including discussions that you have had with your patient about alternative treatments and compliance with the treatment regimen.

30. Q: What is a pain management agreement, and when I required to enter into a pain management agreement with my patient?

A: A pain management agreement is a written agreement between you and your patient that documents your patient's pain management plan. It must be signed and dated prior to the commencement of an ongoing course of treatment for chronic pain with a Schedule II CDS or any opioid. The Board has provided an example of a pain management agreement which includes all the requisite elements. https://www.njconsumeraffairs.gov/prescribing-for-pain/Documents/Pain-Treatment-with-Opioid-Medications-Patient-Agreement.pdf. You are not required to use this specific model, just to include the required elements set forth in FAQ 31, below.

31. Q: What must the pain management agreement contain?

- A: The pain management agreement must:
 - (1.) Document the understanding of both you and your patient regarding the patient's pain management plan.

- (2.) Establish your patient's rights with respect to treatment and his/her obligation concerning his/her responsible use, discontinuation of use, storage and disposal of all controlled substances, refills, and acceptance of similar prescriptions from other prescribers.
- (3.) Identify the specific medications and other modes of treatment that are part of the treatment plan.
- (4.) Specify the steps you may take to monitor the patient's compliance, including random specimen screens and pill counts.
- (5.) Delineate the process for terminating the agreement, including the steps that you can take should the patient fail to comply with the terms of the agreement. For guidance on terminating treatment, see:
 - www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Pain_ Opioid_Taper_Tool_IB_10_939_P96820.pdf; and
 - www.oregonpainguidance.org/wp-content/uploads/2014/04/OPG Guidelines.pdf.

32. Q: Are there patients to whom these requirements do not apply?

A: Yes. These requirements do 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, is a resident of a long term care facility or to any medications that are being prescribed for the treatment of opioid use disorder (for example, methadone or buprenorphine (suboxone)).

33. Q: What should I advise my patient about storage and disposal of their medications?

A: You can alert your patients to the locations of Project Medicine Drop boxes, to DEA Take Back days or advise them to use a drug disposal pouch. You should counsel your patients to store their medications securely, never share with others, and properly dispose of unused and expired medications. Also counsel your patients to take particular care when children are present in their home, and advise of the dangers to children should they have access to opioid medication.

See: www.njconsumeraffairs.gov/meddrop/Pages/Safety.aspx.

34. Q: Is there a continuing education requirement on opioid related topics?

A: Yes. Practitioners are required to obtain one credit of continuing education on topics relating to opioid prescribing, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. Compliance with this requirement is for the biennial renewal cycle commencing July 1, 2019. The Board is in the process of amending its rules to reflect this requirement.

FOR ADDITIONAL INFORMATION REGARDING THE NEW JERSEY PRESCRIPTION MONITORING PROGRAM (NJPMP), VISIT www.njconsumeraffairs.gov/pmp/Pages/default.aspx.