GUIDELINES - - -

What Practitioners Should Discuss With Their Patients.

Under the law[1], practitioners are required to have conversations with a patient about the risks, benefits, and alternatives to opioids, and to document in the patient record that the discussion took place.

Required Discussion

Prior to issuing the initial prescription of a Schedule II controlled dangerous substance or any other opioid drug in a course of treatment for acute or chronic pain, and again prior to issuing the third prescription of the course of treatment, you must discuss with the patient the risks associated with the drugs being prescribed. The content of that discussion should include:

- The reasons why the medication is being prescribed and the treatment goals;
- The possible alternative treatments; and
- The risks associated with the medication; specifically:

  - The risks of developing a physical or psychological dependence or addiction, even when these medications are taken as prescribed;
  - The risk of mixing opioid drugs with alcohol, benzodiazepines and other central nervous system depressants;
  - The risk associated with taking more opioids than prescribed;
  - The risk of driving or operating machinery when taking opioids; and
  - The risk of overdose and potentially fatal respiratory depression.

With respect to unemancipated patients under 18 years of age, this discussion must be with the parents or guardians of the patient, and it must take place prior to the issuance of **every** prescription for a Schedule II opioid, not just the first and third time a prescription is issued. 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.

Although you may give your patient a handout as a supplement to this conversation, you must have a discussion and include a note in the patient record documenting that the discussions took place. When treating patients for chronic pain, you must enter into a pain management agreement, which will provide an important opportunity to reiterate the discussion and establish expectations for long-term prescribing.[2] Effective communication requires that you allow adequate time and ask the patient if they have questions and correct any misunderstandings.[3]

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1 www.njconsumeraffairs.gov/bme/Documents/BME-Rule-Text.pdf - Effective March 1, 2017;

2 www.njconsumeraffairs.gov/prescribing-for-pain/Documents/Pain-Treatment-with-Opioid-Medications-Pain-Agreement.pdf

3 www.njconsumeraffairs.gov/prescribing-for-pain/Documents/BME-Guidelines-What-Patients-Should-Ask-Prescribers-Before-Taking-Opioids.pdf

Additional topics for discussion, which although not mandated by the statute, are consonant with good medical practice and are in the best interest of patients:

Discussion of Treatment Goals

From the outset of treatment it is important that patients understand that you don't know how effective opioids will be over time and that these opioids probably won't take away pain completely. They should also understand that if the medications prescribed are not meeting treatment objectives or are causing side effects or harm, alternatives will be pursued and that you and your patient should be committed to tapering the use of opioids.

Possible Side Effects and Withdrawal Symptoms

As with any medication, you should prepare your patient for possible side effects of treatment, which for opioids can 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.

You should also address the symptoms that may be involved 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.

Ongoing Monitoring

You should let the patient know that you are required to access the Prescription Monitoring Program (PMP) and about the methods you will be using to monitor opioid therapy, whether by random urine screens or pill counts. Discussion of these tools at the outset can avoid having the patient view them as intrusive or evidence of a lack of trust.

Availability of Overdose Antidotes

With patients who are particularly at risk, or who have had a history of substance abuse, you should consider issuing a prescription for naloxone, and educating the patient and family members, if possible, about its use.

Proper Storage and Disposal of Medications

You should counsel your patients to store their medications securely, never share with others, and properly dispose of unused and expired medications. You can alert your patients to Take Back days or Project Medicine Drop locations, or advise them to use a drug disposal pouch. Additional information is available at:

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

www.deadiversion.usdoj.gov/drug_disposal/takeback/

Good medical practice, and the Board's prior rule, always have required practitioners to thoroughly assess patient needs before prescribing controlled substances. The new rule, and the newly enacted statute, are clearer with respect to the general standard of care, and more explicit about the need for, and content of, the discussion that should take place in advance of, and during the course of treatment, and the requirements of ongoing monitoring, including the mandatory use of pain management agreements.

22. Q: ***Does the new rule set forth the 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 non-pharmacological 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. Although *N.J.S.A. 45:1-46.1, the NJPMP statute*, requires prescribers to access NJPMP information only when prescribing Schedule II controlled substances, information about other controlled substances, such as stimulants or benzodiazepines, may have bearing on the treatment decisions to be made.

If you are exempted from the mandatory look-up provisions under N.J.A.C. 13:45A-35.9(c) -- for example, if you are seeing the patient in an emergency department of a hospital, and providing no more than a five-day supply -- you should still consider accessing NJPMP information to better inform your treatment decisions, even though you are not required to do so. When prescribing controlled substance for purposes other than for the treatment of pain -- for example for ADHD, you should also consider accessing the NJPMP.

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.