Overview of the New Board Rules for Chronic Pain Opioid Prescriptions

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On December 23, 2018, Ohio physicians became subject to new rules governing the prescription of opioids to address chronic pain (the “New Rules”). The New Rules do not set limits for the dispensing of opioids but instead set up certain “safety checkpoints” based upon dosages to facilitate further review and communication by physicians.

It is imperative that Ohio physicians understand the New Rules and then implement any necessary changes within their practices to ensure compliance. To support physicians in this effort, this article broadly summarizes the new requirements and identifies certain resources available to physicians who desire more information and support.

Overview of Crisis and Regulatory Landscape

For many years, Ohio has been considered to be at the epicenter of the opioid crisis. Prescription opioids are considered by many to be a key contributor to the epidemic.

Although the availability of prescription opioids for illicit purposes and prescription opioid-related overdose deaths both appear to be decreasing in Ohio, the prevention of illicit prescription opioid use and overdoses through the reduction of prescription (Continued on page 2)
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opioids remains a priority for state and industry leaders. Examples of Ohio initiatives that have been adopted to decrease the availability of prescription opioids include the Ohio Automated Rx Reporting System (“OARRS”), Ohio’s Prescription Drug Monitoring Program (“PDMP”) and the various prescribing guidelines and related resources that have been promulgated.

The State Medical Board of Ohio (the “Board”) continues to fight the opioid crisis by bolstering opioid prescribing requirements intended to help prevent patients from becoming addicted to prescription opioids. The New Rules are the latest example of such efforts.

Summary of New Rules

Applicability

The New Rules govern Ohio physicians’ prescriptions of opioids for the treatment of chronic pain (lasting 12 weeks or more) and subacute pain (lasting between six and 12 weeks). However, note that the New Rules do not apply to opioid prescriptions by physicians to patients in hospice care, inpatients in a hospital, patients with terminal cancer or patients with another terminal condition.

Limiting Prescriptions to the Minimum Necessary

The New Rules require physicians to consider and document non-medication and non-opioid treatment options before treating, or continuing to treat, subacute or chronic pain with an opioid. In the event that the physician determines through a history and physical examination that an opioid prescription is required, the physician must prescribe only the minimum quantity and potency needed to treat the expected duration of pain and improve the patient’s ability to function.

General Documentation Requirements

Before providing an opioid prescription for subacute or chronic pain, Ohio physicians must complete or update the patient record to reflect the following assessment activities:

• History and physical examination (including review of previous treatment and response to treatment, patient’s adherence to medication and non-medication treatment, and screening for substance misuse or substance use disorder);
• Laboratory or diagnostic testing or documented review of any available relevant laboratory or diagnostic test results (note that, if evidence of substance misuse or substance use disorder exists, diagnostic testing shall include urine drug screening);
• Review the results of an OARRS check;
• A functional pain assessment which includes the patient’s ability to engage in work or other purposeful activities, the pain intensity and its interference with daily activities, quality of family life and social activities, and the patient’s physical activity;
• A treatment plan based upon the clinical information obtained, to include all of the following components: (a) diagnosis, (b) objective goals for treatment, (c) rationale for the medication choice and dosage, and (d) planned treatment duration and steps for further assessment and follow-up; and
• Discussion with the patient regarding: (a) benefits and risks of the medication (including potential for addiction and risk of overdose), and (b) the patient’s responsibility to safely store and appropriately dispose of the medication.

During the course of treatment with an opioid prescription with an average dose of less than 50 MED per day, the physician shall provide periodic follow-up assessment and documentation of: (a) the patient’s functional status, (b) the patient’s progress toward treatment objectives, (c) indicators of possible addiction, and (d) drug abuse or drug diversion and the notation of any adverse drug effects.

During the course of treatment with an opioid prescription with an average dose equal to or greater than 50 MED per day, an Ohio physician must complete and document the following in the patient record at least every three months:

• Review of the course of treatment and the patient’s response and adherence to treatment;
• Review of any complications or exacerbation of the underlying condition causing the pain through appropriate interval history, physical examination, any appropriate diagnostic tests, and specific treatments to address the findings;
• Assessment of the patient’s adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities;
• Rationale for continuing opioid treatment and nature of continued benefit, if present;
• Results of an OARRS check;
• Screening for medication misuse or substance use disorder; and
• Evaluation of other forms of treatment and the tapering of opioid medication if continued benefit cannot be established.

Safety Checkpoints

50 MED or More

Before increasing an opioid prescription to a daily average of 50 MED or greater, Ohio physicians need to complete each of the following:

• Enter into a written pain treatment agreement with the patient that outlines the physician’s and patient’s responsibilities during treatment and requires the patient’s agreement to each of the following provisions:
  o Permission for drug screening and release to speak with other practitioners concerning the patient’s condition or treatment;
  o Cooperation with pill counts or other checks designed to assure compliance with the treatment plan and to minimize the risk of misuse or diversion;
  o The understanding that the patient shall only receive opioid medications from the physician treating the chronic pain unless there is written agreement among all of the prescribers of opioids outlining the responsibilities and boundaries of prescribing for the patient; and
  o The understanding that the dosage may be tapered if not effective or if the patient does not abide by the treatment agreement.

A template pain management agreement that can be utilized for this purpose can be found on the Board website.

Further, unless the patient was prescribed an average daily dosage that exceeded 50 MED before December 23, 2018, the physician must document consideration of each of the following: (a) consultation with a specialist in the area of the body affected by the pain; (b) consultation with a pain management specialist; (b) obtaining a medication therapy management review by a pharmacist; and (d) consultation with a specialist in addiction medicine or addiction psychiatry, if medication misuse or substance use disorder are noted.

The physician is also required to consider offering a prescription for naloxone to mitigate risk of overdose.

80 MED or More

Before increasing an opioid prescription to a daily average of 80 MED or greater, Ohio physicians also need to complete each of the following:

• Consultation with a specialist in addiction medicine or addiction psychiatry, if medication misuse or substance use disorder is present.

Further, unless the patient was prescribed an average daily dosage that exceeded 80 MED before December 23, 2018, the physician must document consideration of each of the following: (a) consultation with a specialist in the body area affected by the pain; (b) consultation with a pain management specialist; (c) a medication therapy management review; and (d) consultation with a specialist in addiction medicine or addiction psychiatry if medication misuse or substance use disorder is present.

120 MED or More

Ohio physicians are prohibited from prescribing a dosage that exceeds an average of 120 MED per day, unless one of the following circumstances applies:

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• The physician holds board certification in pain medicine or in hospice and palliative care;
• The physician has received a written recommendation for a dosage in excess of an average of 120 MED per day from a board certified pain medicine physician or hospice and palliative care physician who based the recommendation on a face-to-face visit and examination of the patient (and the prescribing physician shall maintain the written recommendation in the patient’s record); or
• The patient was receiving an average daily dose of 120 MED or more prior to December 23, 2018. However, note that, in the event that a physician escalates the patient’s dose, the physician has to again obtain and document the written recommendation in accordance with the prior bullet point.

Naloxone Prescriptions
Finally, note that Ohio physicians are required to offer a naloxone prescription to patients receiving an opioid prescription under any of the following circumstances: (a) the patient has a history of prior opioid overdose; (b) the dosage prescribed exceeds a daily average of 80 MED or at lower doses if the patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodal, tramadol, or gabapentin; or (c) the patient has a concurrent substance use disorder.

Conclusion
Because federal and state opioid prescribing requirements, and the guidance with respect to the government’s enforcement of those laws, is continually growing and changing, physicians must stay abreast of developments in this area. It’s imperative that Ohio physicians understand the New Rule and implement changes to their clinical and documentation protocols and other procedures as necessary to ensure compliance. The Board, the Centers for Disease Control and Prevention (“CDC”), the Academy of Medicine of Cleveland & Northern Ohio (AMCNO), other professional associations and legal advisors are all excellent sources of continuing medical education, template documents and other educational information regarding the prescription of opioids for chronic pain.

References