

New Limits on Prescription Opioids for Acute Pain



Frequently Asked Questions

1. What are Ohio's acute pain prescribing rules?

The Medical Board's acute pain prescribing rules are made up of three parts:

- Rule 4731-11-01, Ohio Administrative Code (OAC), defines such terms as "acute pain," Morphine equivalent daily dosage (MED)," "opioid analgesic," and other terms.
- Rule 4731-11-02, OAC, requires a prescription to comply with Pharmacy Board rules setting requirements for the content of a prescription.
- Rule 4731-11-13, OAC, sets requirements for the prescribing of opioid analgesics for the treatment of acute pain.

The rules apply to the prescribing of an opioid analgesic for the treatment of acute pain in an out-patient setting. The rules do not apply to the treatment of acute pain in an in-patient setting, treatment of chronic pain, treatment of a hospice patient, treatment of a palliative care patient, treatment of a person who has been diagnosed with a terminal condition, treatment of a cancer patient, or treatment of opioid addiction using a controlled substance approved for that purpose by the FDA.

Similar rules for acute pain prescribing have been adopted by the Ohio State Dental Board and the Ohio Board of Nursing.

2. What is the purpose of the rules?

The acute pain prescribing rules reflect the policy of the State of Ohio that when it is necessary to treat acute pain with an opioid analgesic, the prescription should be for the shortest number of days and lowest dosage required to treat the acute pain.

3. In what situations would a prescription be considered an "inpatient prescription"?

As defined by Rule 4729-17-01, "inpatient" means any person who receives drugs for use while within the institutional facility and "inpatient prescription" means a written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient. The dosage limits do not apply to treatment of pain during a patient's hospital stay.

Institutional facility means a hospital, convalescent home, developmental facility, long term care facility, nursing home, psychiatric facility, rehabilitation facility, developmental disability facility and Level III sub-acute detoxification facility.



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4. Are the acute pain opioid prescribing rules for physician assistants as well?

The rules are applicable to physician assistants for two reasons:

1. The Medical Board's rules regarding controlled substance prescribing in Chapter 4371-11, OAC, apply to physician assistants. See, Rule 4730-2-07, OAC
2. The Physician Assistant Practice Act provides that a physician assistant may not prescribe beyond the authority of the supervising physician. A supervising physician may not authorize a physician assistant to provide prescriptive services in a way that is incompatible with the services within the physician's normal course of practice. See 4730.02(D)(2), ORC. See also 4730.21(C), ORC. Accordingly, the supervising physician may not authorize the physician assistant to prescribe for a greater number of days' supply or greater dosage than the supervising physician may prescribe.

In addition, a physician assistant must comply with the Physician Assistant Formulary.

5. Do the rules apply to nurse practitioners?

Advanced practice registered nurses, including nurse practitioners, must comply with Nursing Board Rule 4723-9-10, OAC.

6. Do the rules apply to Ohio licensed physicians/physician assistants who don't practice in Ohio, but do practice in another state?

No, the rules do not apply if the physician or physician assistant is not practicing under their Ohio license. For example:

- The rules are NOT applicable to an Ohio-licensed physician or physician assistant who is practicing in another state under a medical license issued by that other state.
- The rules ARE applicable to an Ohio-licensed physician or physician assistant who is based in another state but who is providing medical services via telemedicine to a patient located in Ohio. In this example, the practice occurs in Ohio under the Ohio license because the patient is located in Ohio at the time medical service is rendered.

7. I am a physician assistant (PA). Does Rule 4731-11-13 override the Physician Assistant Formulary?

No, the PA Formulary must still be followed in accordance with OAC 4731-11-13 and ORC 4730.41. A general summary of a physician assistant's ability to prescribe scheduled drugs to treat acute pain is as follows:



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OPIOID ANALGESICS OTHER THAN SCHEDULE II DRUGS:

The PA who holds a valid prescriber number and DEA registration may prescribe the opioid analgesic as authorized to do so by the supervising physician, and health care facility policy, if applicable, in compliance with the acute pain rules. This includes the ability to write for longer than a seven-day supply or dosage greater than a 30 MED average per day.

SCHEDULE II OPIOID ANALGESICS:

IN A HOSPITAL or other location specified in ORC 4730.411(B)(2) through (12): A PA who holds a valid prescriber number and DEA registration may prescribe a Schedule II drug for the treatment of acute pain in compliance with the acute pain prescribing rules, when authorized to do so by the facility's policies and the supervising physician.

IN A MEDICAL PRACTICE OWNED BY ONE OR MORE PHYSICIANS TO PROVIDE DIRECT PATIENT CARE, WHERE THE SUPERVISING PHYSICIAN IS ONE OF THE OWNERS AND PRIMARILY PRACTICES AT THAT LOCATION:

- Prescription initiated by the PA without supervising physician involvement: A PA who holds DEA registration may only write one prescription for no more than a seven-day supply of a Schedule II opioid analgesic. The PA may not write the prescription for longer than seven days or write a second prescription to the patient.
- Prescription initiated by the physician or by the PA after consultation with the physician: A PA may write a prescription for more than a seven-day supply in compliance with OAC 4731-11-13(A)(3)(a)(iii). For subsequent prescriptions to the patient the physician assistant may not change the drug or dosage unless there is documentation in the patient record that the supervising physician approved the change(s).

- 8. Following a routine surgical procedure in my office, I gave the patient a three-day supply of a Schedule III opioid analgesic to treat the pain. If the patient calls to ask for another prescription because the pain has not subsided does the rule allow me to prescribe the patient another prescription for an opioid analgesic?**

Yes, you would be able to write a subsequent prescription for an opioid analgesic. However, the prescription should be written for the fewest number of days and lowest dosage required to treat the pain.

- 9. Does the rule require that the patient come into the office before another prescription for an opioid analgesic may be written to treat their acute pain?**

No, the rule does not require that the patient come into the office before receiving a subsequent prescription for an opioid analgesic. The determination of whether the patient should be seen in the office should be made based upon the medical condition or injury, the status of the patient, and other considerations for appropriate medical care.



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10. What documentation is needed to support writing an opioid analgesic prescription for longer than seven days for an adult/five days for a minor or a prescription greater than 30 MED?

- When the physician or physician assistant believes that a patient needs a new, acute-pain related opioid that exceeds the 7/5 day or the 30 MED rule, the documentation should provide a rationale within the progress note that explains the justification for it. This could be brief information about the actual condition or treatment which necessitates more than the recommended MED or duration of treatment.
- The documentation should indicate whether there are known and available non-opiate alternatives, and why it has been determined not to utilize these alternatives.
- Should a patient have a known history of narcotic use, the physician or physician assistant should document the reason for acute opioid needs versus known chronic pain.
- The first four characters of the ICD-10 code should be noted in the progress note and, starting on December 29, 2017, written on the prescription.
- As per current standards, review of an OARRS report should be documented.
- Documentation of planned follow up with the patient.

11. How does the rule's requirement to obtain adult consent before prescribing to a minor an opioid analgesic for acute pain square up with the provisions of Section 3719.061 of the Ohio Revised Code that exempt care in hospitals and certain other settings from a similar requirement?

It is not necessary to obtain written consent from an appropriate adult before prescribing an opioid analgesic to a minor in situations that are exempt from this requirement in Section 3719.061(C). However, the exemptions in that statute do not apply to the five-day limit or dosage limit. There must be compliance with the five-day limit and 30 MED average per day dosage limit provisions in Rule 4731-11-13.

12. Am I able to prescribe an extended-release or long-acting opioid analgesic to treat acute pain following a medical procedure for which the journals support that the patient will likely experience a high degree of pain?

No. Rule 4731-11-13 prohibits prescribing an extended-release or long-acting opioid analgesic for the treatment of acute pain.

13. Do the rules apply when a patient, who is prescribed an opioid analgesic for chronic pain, sustains an injury or undergoes surgery for which acute pain medication is appropriate?

Yes, the rules apply to all prescriptions for out-patient treatment of acute pain. Where the patient is already on an opioid analgesic for chronic pain, it is suggested that, the physician or physician



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assistant confer with the prescriber for the chronic pain and document the results to support the acute pain prescription. The prescription for acute pain should be for the lowest dosage and shortest number of days required to treat the acute pain episode.

14. Do the rules allow for the prescribing of an opioid analgesic to a patient with sickle cell anemia who is already prescribed an opioid analgesic for chronic pain but who then experiences a sickle cell crisis resulting in acute pain if the combined dosage of the medication for the chronic and acute pain will be greater than 30 MED?

Yes, but the physician or physician assistant must document that exceeding the 30 MED limit is necessary based on clinical judgment and the patient's needs and the reason the dosage is the lowest dosage consistent with the patient's medical condition. When possible, the chronic pain prescriber should be consulted, with the results documented to support the dosage prescribed. However, the prescription for acute pain must be limited to no more than the number of days required to treat the expected duration of the pain, with the required documentation made if the number of days exceeds five for a minor or seven for an adult patient.

15. If I have written the first opioid analgesic prescription for longer than seven days (adult patient) or five days (minor patient), may a cross-covering or on-call physician or physician assistant write the patient another prescription?

Yes. A cross-covering or on-call physician or physician assistant may write the patient another prescription for an opioid analgesic to treat acute pain. However, the subsequent prescription should be written for the shortest number of days and lowest dosage required to treat the acute pain.

16. If I have written the first opioid analgesic prescription for a dosage above a 30 MED average per day, may a cross-covering or on-call physician or physician assistant write the patient another prescription for a dosage greater than 30 MED average per day?

No. Rule 4731-11-13(A)(3)(c)(iv) authorizes only the original prescriber to exceed the 30 MED average per day limit. The original prescriber should ensure that he or she is available to patients who may have a severe acute injury or condition for which the dosage may need to exceed the 30MED. An in-person reassessment may also be necessary for patients experiencing escalating pain.



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17. Are the “treating physician” and “prescribing physician” in Rule 4731-11-13(A)(3)(c) the same individual?

The language of paragraph (A)(3)(c) states that the treating physician determines, based upon prevailing standards of medical care, that the patient suffers from medical conditions, surgical outcomes, or injuries of such severity that pain cannot be managed with the 30 MED average limit. The treating physician must document in the record the reason for exceeding the 30 MED average. However, the rule then states that the only “prescribing physician” may exceed the 30 MED average and will be held singularly accountable for the prescription.

As used in 4731-11-13(A)(3)(c)(i) through (v), the term “prescribing physician” must be read to mean “treating physician.” Only the treating physician may write a prescription for a dosage above the 30 MED average per day limit. The treating physician must also write any subsequent prescriptions for the patient that are for a dosage above the 30 MED average per day limit.

18. Is there a preference between prescribing a drug containing hydrocodone or one containing oxycodone?

The acute pain prescribing rules do not specify the drugs that may be prescribed for post-surgical, out-patient usage by the patient. The rule does, however, prohibit the prescribing of long-acting or extended-release opioid analgesics for the treatment of acute pain.

18. What additional documentation is required on the prescription for an opioid analgesic for the treatment of acute pain?

Beginning December 29, 2017, all prescriptions for an opioid analgesic must include the first four characters of the ICD-10 code for the condition being treated. Also, beginning December 29, 2017 a prescription for any controlled substance, including an opioid analgesic, must also include the number of days for which the medication is being prescribed.

19. Does Rule 4731-11-13 apply to a liquid form of an opioid analgesic?

The rule does not apply to a liquid form of an opioid analgesic that is used for a purpose other than the treatment of pain. For example, the rule does not apply to the prescription of cough medications that contain an opioid analgesic.

20. Is it permissible to treat acute pain by writing an opioid analgesic prescription for seven days, but include a refill for another seven days in case the patient requires it?



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No. Rule 4731-11-13 prohibits a physician or physician assistant from giving a refill on the first prescription written for the outpatient treatment of acute pain.

21. I practice at a Veterans Administration medical center or at a military facility in my capacity as an active duty member of a military service. Do I have to comply with the acute pain prescribing rules?

The acute pain rules do not apply to a physician or physician assistant while practicing at a U.S. Veterans Administration facility or while practicing at a military facility while serving on active military duty.

22. Rule 4731-11-13 provides a mechanism for prescribing a dosage greater than a 30 MED average per day and lists four types of conditions. Are these the ONLY conditions for which a dosage greater than 30 MED average per day or longer than 7/5 days may be written?

The acute pain prescribing rules reflect the policy of the State of Ohio that when it is necessary to treat acute pain with an opioid analgesic the prescription should be for the shortest number of days and lowest dosage required to treat the acute pain. However, there is also a recognition that there are situations where the pain is of such severity that it cannot be managed within the 30 MED or in 7/5 days. The four conditions listed in paragraph (A)(3)(c)(i) of Rule 4731-11-13 were provided as examples. There are many other types of conditions, surgical outcomes, or injuries for which the treating physician or physician assistant might determine, based upon prevailing standards of medical care, that an opioid analgesic with a dosage greater than 30 MED average or 7/5 days is appropriate. The Medical Board will not be creating a listing of reasons; clinical judgement and documentation should be used in those situations.

23. For purposes of Rule 4731-11-13's language providing that the dosage may be greater than 30 MED average per day in certain situations, how are "major orthopedic surgery" or "severe burns" defined?

The rules do not define "major orthopedic surgery" or "severe burns." The terms should be interpreted as surgery or burns of such severity that pain cannot be managed within the 30 MED average limit as determined based upon the prevailing standards of medical care.

24. If the patient's procedure warrants more than 30 MED, what is the maximum MED per day that can be prescribed to treat post-operative acute pain?



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Rule 4731-11-13 does not set a maximum MED per day that can be prescribed to treat post-operative, out-patient acute pain or other similar exceptions. For dosages greater than 30 MED average per day, the documentation must include the reason for exceeding the 30 MED average and the reason the dosage being prescribed is the lowest dosage consistent with the patient's medical condition. Prescriptions that exceed the 30 MED average daily dosage are subject to additional review by the Medical Board.

25. If the patient's pain is anticipated to last longer than 7/5 days, what is the maximum period for which an opioid analgesic may be prescribed to treat acute pain?

Rule 4731-11-13 does not set a maximum number of days for which an opioid analgesic prescription may be written to treat acute pain in situations where the prescriber's clinical judgement determines more than 7/5 days is necessary. The number of days should always be the fewest number needed to treat the expected duration of the acute pain. The reason that the number of days exceeds seven for an adult or five for a minor and the reason why a non-opioid medication is not appropriate to treat the pain must be documented in the patient medical record. Prescriptions that exceed the 7/5 day limit are subject to additional review by the Medical Board.

26. When writing an opioid analgesic prescription to treat a hospice patient's acute pain is it required that I note on the prescription that it is for a hospice patient?

The prescription should include the first four characters of the ICD-10 code for the condition being treated as acute pain. Starting on December 29, 2017 this information will be required on all prescriptions for opioid analgesics, and will be required on all controlled substance prescriptions starting on June 1, 2018. The ICD-10 code may indicate that the patient's conditions is terminal or that the patient is receiving hospice care.

If a pharmacist calls concerning an opioid analgesic prescription that is written for more than 7/5 days or for a dosage greater than 30 MED average per day, it is appropriate for the prescribing physician or physician assistant to advise the pharmacist that the patient is a hospice patient.

27. How do I determine the MED equivalent of an opioid analgesic?

The Pharmacy Board has a MED calculator available on the OARRS website:
ohiopmp.gov/MED_Calculator.aspx



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