BOARDS AND COMMISSIONS

Kentucky Board of Medical Licensure

(Amendment)

201 KAR 9:270. Professional standards for prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone.

RELATES TO: KRS 218A.205, 311.530-311.620, 311.840-311.862, 311.990

STATUTORY AUTHORITY: KRS 311.565(1)(a)

CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB 6, Section 8.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licensees. KRS 218A.205(3)(a) and (b) require the board to establish mandatory prescribing and dispensing standards related to controlled substances. KRS 311.842(1)(b) requires that the board promulgate administrative regulations establishing professional standards for prescribing and administering controlled substances by physician assistants. This administrative regulation establishes the professional standards for any board licensee who prescribes, dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky. Nothing within this administrative regulation shall be interpreted to grant physician assistants authority to dispense Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone, unless otherwise authorized by KRS 311.842.

Section 1. Applicability.

(1) Any licensee who prescribes, dispenses or administers, dispenses Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall comply with the standards of acceptable and prevailing medical practices established in this administrative regulation.

(2) A physician assistant shall only prescribe or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to the extent delegated by the supervising physician in the applications required under KRS 311.854 and 311.858. This administrative regulation, including any exemptions stated herein, shall not alter the prescribing limits established in KRS 311.858 or the requirement for delegation from a supervising physician established in KRS 311.854.

(a) Any change in the supervising physician application, including changes in practice address, scope of practice, or scope of delegated prescriptive authority, required under KRS 311.854 and 311.858 shall be reported in writing to the board within ten (10) days of the change.

(b) If the physician assistant's supervising physician changes or the supervising physician become restricted or suspended from the practice of medicine or osteopathy, the physician assistant shall cease prescribing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone until the restriction or suspension is terminated or a new supervising physician is approved.

(c) Prescribing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone without the applications required under KRS 311.854 and 311.858 shall constitute a violation of this administrative regulation and shall be grounds for an emergency order of restriction or suspension.

(3) The professional standards established in this administrative regulation shall not apply to prescribing or dispensing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone:

(a) To a patient as part of the patient's hospice or end-of-life treatment;

(b) To a patient admitted to a hospital-based or hospital-affiliated emergency department while the patient is admitted therein;

(c) To a patient admitted to a licensed hospital, during and as part of a normal and expected part of the patient's course of care at that hospital;

(d) To a patient who is admitted to a level 3.5 or higher inpatient residential treatment facility with an on-sight medical director who is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine in addiction medicine, the American Board of Medical Specialties (ABMS) in addiction medicine, or an American Osteopathic Association (AOA) certifying board in addiction medicine, during and as part of a normal and expected part of the patient's course of care at that facility;

(e) To a patient who is a registered resident of a long-term care facility as defined in KRS 216.510; and

(f) For up to fourteen (14) days, to a patient who has undergone a major surgery, being any operative or invasive procedure or delivery, or has suffered a significant physical trauma, being any acute, blunt, blast or penetrating bodily injury that has a risk of death, physical disability or impairment.

Section 2. Minimum Qualifications.

(1) A licensee shall not prescribe, dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone unless that licensee possesses the minimum qualifications established in this section.

(2) The licensee shall successfully complete the approved educational programs required by this subsection.

(a) The prescribing licensee shall be a DEA-licensed prescriber of controlled substances, including Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, and shall have completed any and all courses deemed necessary by the DEA.

(b) For each three (3) year continuing education cycle, each DEA-licensed prescriber of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall complete at least twelve (12) hours of continuing medical education certified in Category I specific to addiction medicine as part of the required continuing medical education hours set forth in 201 KAR 9:310 and 201 KAR 9:360.

Section 3. Professional Standards for Prescribing, Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for Medically-Supervised Withdrawal or the Treatment of Opioid Use Disorder.

(1)

(a) Except as provided in paragraph (b) of this subsection, transmucosal Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall only be prescribed, dispensed, or administered for medically-supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid use disorder.

(b) Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall not be used for the treatment of pain or any other condition, unless delivered in a Federal Drug Administration (FDA) approved form and for an FDA approved purpose.

(2) Buprenorphine-Mono-Product shall not be prescribed, dispensed, or administered for medically-supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid use disorder, except:

(a) To a pregnant patient;

(b) To a patient with demonstrated hypersensitivity to naloxone; or

(c) As administered under supervision in a physician's office or other healthcare facility, including hospitals, urgent care settings, surgical care centers, residential treatment facilities, and correctional facilities.

(3) If Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone is prescribed, dispensed, or administered to a patient who is also being prescribed other controlled substances or other substances subject to abuse or misuse beyond a period of three (3) months, then the licensee shall obtain and document a formal provider-to-provider or patient-to-provider consultation of a physician who is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine in addiction medicine, the American Board of Medical Specialties (ABMS) in addiction medicine, or an American Osteopathic Association (AOA) certifying board in addiction medicine or a physician who has completed an addiction psychiatry fellowship.

(4) Each licensee who prescribes, dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for medically-supervised withdrawal or for the treatment of opioid use disorder shall fully comply with the professional standards established in this subsection.

(a) Prior to or at least within two (2) weeks of initiating treatment, the prescribing, dispensing, or administering licensee shall:

1. Obtain and record a complete and appropriate evaluation of the patient which shall at a minimum include:

a. The patient's history of present illness;

b. The patient's history of substance use;

c. The patient's social and family history;

d. The patient's past medical and psychiatric histories;

e. A focused physical examination of the patient;

f. Offer screening with counseling for HIV and hepatitis serology; and

g. Arranging appropriate laboratory tests, which shall include a CBC, a drug screen, and a CMP;

2. Obtain the patient's consent and authorizations in order to obtain the patient's prior medical records.

a. Upon receipt of the medical records, the prescribing, dispensing, or administering licensee shall review and incorporate the information from the records into the evaluation and treatment of the patient.

b. If the prescribing, dispensing, or administering licensee is unable, despite best efforts, to obtain the patient's prior medical records, the licensee shall document those efforts in the patient's chart;

3. Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the initial patient encounter and appropriately utilize that information in the evaluation and treatment of the patient;

4. Explain treatment alternatives and the risks and the benefits of treatment with Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to the patient;

5. Obtain written informed consent from the patient in a manner that meets professional standards; and

6. If the patient is a female of child-bearing age and ability, the licensee shall offer to screen for pregnancy and provide counseling as to the risk of neonatal abstinence syndrome which shall be consistent with current SAMHSA guidance. If the patient is pregnant, the prescribing, dispensing, or administering licensee shall refer the patient to an obstetrician or maternal-fetal medicine specialist for prenatal care, unless the licensee assumes management of the prenatal care.

(b) Except as provided by paragraph (d) of this subsection, while initiating treatment with Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, the licensee shall comply with the requirements of this paragraph.

1. The licensee shall recommend to the patient an in-office observed initiation protocol, particularly if the patient is on fentanyl or methadone.

a. Except as provided in clause b. of this subparagraph, the licensee shall supervise the in-office observed initiation protocol and shall ensure that resources are available to manage precipitated withdrawal.

b. If an in-office observed initiation does not occur, the licensee shall appropriately record the circumstances in the patient chart and shall educate the patient about the potential for precipitated withdrawal. The licensee shall be responsible for the coordination and implementation of a plan to manage precipitated withdrawal outside of an in-office observed initiation.

2. The licensee shall assess for and document the presence or absence of opioid withdrawal before the first dose is given by using a standardized instrument, such as the clinic opioid withdrawal scale (COWS) or other similarly recognized instrument.

3. The licensee shall initiate treatment with a dose not to exceed the dose equivalency of four (4) milligrams buprenorphine generic tablet, which:

a. May be followed by subsequent doses; and

b. Shall not exceed the dose equivalency of sixteen (16) milligrams buprenorphine generic tablet on the first day of treatment.

(c) If the patient is transferred from another treatment provider and has previously experienced withdrawal without a relapse and has not had a lapse in treatment, the licensee shall:

1. Not rely solely on the patient's self-reported history but shall comply with the standards set forth in Section 2(4) of this administrative regulation;

2. Make reasonable attempts to obtain records from the prior treatment provider;

3. Educate the patient about the potential for precipitated withdrawal; and

4. Make an informed and independent clinical decision to continue maintenance treatment of the patient on the same or less dosage as established by the previous treatment provider and then as provided in paragraph (e) of this subsection.

(d) After initial initiation of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, the licensee shall meet the requirements established in this paragraph.

1. If the licensee prescribes, dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone medication, the licensee shall implement a treatment plan that requires objective behavioral modification by the patient. The behavioral modification shall include the patient's participation in a behavioral modification program that may include counseling or a twelve (12) step facilitation.

2. The licensee shall prescribe, dispense, or administer to the patient an amount of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone that:

a. Is necessary to minimize craving and opiate withdrawal;

b. Does not produce opiate sedation; and

c. Is to be taken no more frequently than twice daily; and

d. Is able only to supply the patient until the next licensee visit, which shall be scheduled as required by subparagraph 3. of this paragraph.

3.

a. The licensee shall ensure that the patient is seen by a licensed clinical healthcare professional with prescribing authority:

(i) No later than ten (10) days after initiation and then at intervals of no more than ten (10) days for the first month after initiation; and

(ii) At intervals of no more than fourteen (14) days for the second month after initiation.

b.

(i) If the patient demonstrates objective signs of treatment progress, the licensee shall ensure that the patient is seen at least once monthly thereafter.

(ii) If two (2) years after initiation of treatment, the patient is being prescribed Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for opioid use disorder and the patient has demonstrated objective signs of treatment progress, including documented evidence that the patient has been compliant with the treatment plan and all treatment directives for at least two (2) years, then the licensee may require that the patient be seen only by the licensee at least once every three (3) months.

(iii) The licensee shall see the patient in shorter intervals if the patient demonstrates any noncompliance with the treatment plan.

c. If extenuating circumstances arise that require a patient to unexpectedly reschedule a physician visit, the licensee shall make best efforts to see the patient as soon as possible and document the circumstances in the patient chart.

4. At least every three (3) months after initiation of treatment, the licensee shall evaluate the patient to determine whether the patient's dosage should be continued or modified and shall appropriately document that evaluation and clinical reasoning in the patient's chart.

5. At least once every three (3) months, the licensee shall obtain KASPER reports to help guide the treatment plan.

a. If the KASPER indicates any unexpected findings, the licensee shall incorporate those findings into appropriate clinical reasoning to support the continuation or modification of treatment and shall accurately document the same in the patient record.

b. Appropriate clinical reasoning may include adjustment of dose strength, adjustment of frequency of visits, increased drug screening, a consultation with a specialist, or an alternative treatment.

c. Every twelve (12) months following initiation of treatment, if a patient's prescribed daily therapeutic dosage exceeds the dose equivalency of sixteen (16) milligrams buprenorphine generic tablet per day and the licensee is not certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine in addiction medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry, then the licensee shall refer the patient for a formal consultation with a physician who is certified by the American Board of Addiction Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or a physician who has completed an addiction psychiatry fellowship for an opinion as to whether continued treatment and dosage is appropriate and shall accurately document the results of that consultation in the patient chart. The formal consultation may occur via telehealth if it would meet the same standards of acceptable and prevailing evaluative practices of a physical in-person evaluation.

d. The licensee shall adjust dosages according to the individual patient's condition and within acceptable and prevailing medical standards, with the goal of improving the patient's quality of life and ability to function in the community.

e. Every twelve (12) months following initiation of treatment, the licensee shall evaluate for and document the medical necessity for continued treatment at the established dose.

f. The licensee shall ensure that the patient is drug tested. A patient in early stages of treatment shall be tested at least once weekly and as the patient becomes more stable in treatment, the frequency of drug testing may be decreased, but shall be performed at least on a monthly basis. Individual consideration may be given for less frequent testing if a patient is in sustained remission. If the patient returns to

substance use after a period of abstinence, the licensee shall resume the early treatment testing schedule, in conjunction with an adapted or intensified treatment plan.

(i) Except as in this subclause, each drug screen shall at a minimum screen for buprenorphine, methadone, opioids, THC, benzodiazepines, amphetamines, and cocaine. On intake and at least once a year thereafter, the licensee shall obtain a random and unannounced comprehensive drug screen that shall also screen for gabapentin and illicit substances commonly used in the geographical region.

(ii) If a drug screen indicates any unexpected findings, the licensee shall incorporate those findings into appropriate clinical reasoning to support the continuation or modification of treatment and shall accurately document the same in the patient record.

(iii) Appropriate clinical reasoning may include adjustment of dose strength, adjustment of frequency of visits, increased drug screening with urine confirmation, a consultation with a specialist, or an alternative treatment.

6. If at any time during treatment, the licensee observes patterns of unexpected results in the patient's urine drug screens or KASPER data, then the licensee shall:

a. Refer the patient out to a higher level of care; or

b. Increase the intensity of treatment and continue to monitor for unexpected urine drug screen results and KASPER data.

7. The licensee shall document a plan for handling any lost or stolen medication, which shall not provide for the automatic replacement of medication prior to the specified interval date.

Section 4. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes, and Monitoring.

(1) Each licensee prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the licensee is conforming to professional standards for prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone and other relevant professional standards set forth in this administrative regulation.

(2) If a licensee is unable to conform to professional standards for prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone as set forth in this administrative regulation due to circumstances beyond the licensee's control, or the licensee makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the licensee shall document those circumstances in the patient's record and only prescribe, dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone to the patient if the patient record appropriately justifies the prescribing, dispensing, or administering of Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone under the circumstances and in accordance with SAMHSA guidelines as set forth in: Substance Abuse and Mental Health Services Administration, Medications for Opioid Use Disorder, Treatment Improvement Protocol (TIP) Series 63, Publication No. PEP21-01-002, Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

Section 5. Violations. Failure to comply with or a violation of the professional standards established in Sections 2, 3, and 4 of this administrative regulation shall constitute a "departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky," in violation of KRS 311.850(1)(p) and (s), KRS 311.595(12) and (9), as illustrated by KRS 311.597(4), and may constitute a

violation of KRS 311.595(9), as illustrated by KRS 311.597(3), subjecting the licensee to sanctions authorized by KRS 311.595 and 311.850.

Section 6. Incorporation by Reference.

(1) Substance Abuse and Mental Health Services Administration, "Medications for Opioid Use Disorder, Treatment Improvement Protocol (TIP) Series 63, Publication No. PEP21-01-002", 2021.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, Monday through Friday, 8:00 a.m. to 4:30 p.m.

(3) This material may also be obtained on the board's website at kbml.ky.gov.

WILLIAM C. THORNBURY, M.D., President

APPROVED BY AGENCY: December 12, 2024

FILED WITH LRC: April 11, 2025 at 11:32 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on Friday, June 27, 2025, at 9:00 a.m., using the Kentucky Board of Medical Licensure Zoom meeting room. A Zoom link will be posted on the agency’s website, kbml.ky.gov, prior to the meeting. Individuals interested in being heard at this hearing shall notify this agency in writing no less than five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received at least five (5) workdays prior to the hearing, the hearing may be cancelled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation. Written comments previously submitted will be considered and new comments shall be accepted through June 30, 2025. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

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