GENERAL GOVERNMENT CABINET

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

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

STATUTORY AUTHORITY: KRS 311.565(1)(a)

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. A [~~for Prescribing, Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. Except as provided in Section 3 of this administrative regulation,~~] 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.

[~~(1) The licensee shall obtain and maintain in good standing a waiver and license as issued by the Drug Enforcement Administration (DEA) to prescribe Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for the treatment of opioid use disorder in the Commonwealth of Kentucky.~~]

(1) [~~(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 [~~obtained Buprenorphine certification through completion of a Substance Abuse and Mental Health Services Administration ("SAMHSA") certified course~~].

(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.

[~~(3) The licensee shall enroll in the Kentucky Health Information Exchange to the extent necessary to query and pull information from the Kentucky Health Information Exchange. The licensee shall not report the prescribing, dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for medically supervised withdrawal or as maintenance treatment for a patient diagnosed with opioid use disorder into the Kentucky Health Information Exchange unless otherwise required by law.~~]

Section 3 [2]. 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 [~~; or~~

~~(d) To a patient transitioning from methadone to buprenorphine, limited to a period of no longer than one week~~].

(3) If [~~(a) Except as provided in paragraph (b) of this section,~~] Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone is [~~shall not be~~] 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 [~~benzodiazepines, other sedative hypnotics, stimulants or other opioids without~~] 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 [~~psychiatry~~], or an American Osteopathic Association (AOA) certifying board in addiction medicine or a physician who has completed an addiction psychiatry fellowship [~~psychiatry~~].

[~~(b) A licensee may prescribe, dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to a patient who is also being prescribed benzodiazepines, other sedative hypnotics, stimulants, or other opioids, without consultation in order to address an extraordinary and acute medical need not to exceed a combined period of thirty (30) days.~~]

(4) [~~Except as provided in Section 3 of this administrative regulation,~~] 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, [~~meet the requirements of paragraph (b) of this subsection.~~

~~(b) Except as provided in Section 3 of this administrative regulation, the requirements of this paragraph shall apply to the treatment of a female of child-bearing age and ability.~~

~~1. Prior to initiating treatment, the licensee shall require that the patient submit to a pregnancy test and, if pregnant,~~] 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.

[~~2. a. Unless the licensee is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry or an obstetrician or maternal-fetal medicine specialist, a licensee who prescribes, dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to a patient who is pregnant or breastfeeding shall first obtain and document consultation with another independent physician that the potential benefit of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone use outweighs the potential risk of use.~~

~~b. The consultation shall be obtained from a physician who is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry or from an obstetrician or maternal-fetal medicine specialist.~~]

(c) 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 [~~induction~~] 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 [~~induction~~] protocol and shall ensure that resources are available to manage precipitated withdrawal.

b. If an in-office observed initiation [~~induction~~] 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 [~~if withdrawal persists~~]; and

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

(d) 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 regulation;

2. [~~1. Document that fact~~] Make reasonable attempts to obtain records from the prior treatment provider;

3. [~~2.~~] Educate the patient about the potential for precipitated withdrawal; and

4. [~~3.~~] 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.

(e) After initial initiation [~~induction~~] 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. [~~Except as provided in subclauses (i) through (iv) of this clause,~~] Is to be taken no more frequently than twice [~~once~~] daily;

~~[(i) If the patient is pregnant, is to be taken no more than twice daily;~~

~~(ii) If the patient is receiving a daily dosage of less than 16mg, is to be taken no more than twice daily;~~

~~(iii) If the patient is simultaneously engaged in cancer treatment, hospice or palliative care, is to be taken bid or tid; or~~

~~(iv) If the patient is undergoing 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, is to be taken bid or tid for up to fourteen (14) days;~~] 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 [~~induction~~] and then at intervals of no more than ten (10) days for the first month after initiation [~~induction~~]; and

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

b.

(i) If the patient demonstrates objective signs of [~~positive~~] 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 [~~positive~~] 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 [~~abnormal~~] 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 [~~obtain~~] refer the patient for a formal consultation with [~~from~~] 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 subsection (a), each drug screen shall at a minimum screen for buprenorphine, methadone, opioids, THC, benzodiazepines, amphetamines, and cocaine.

(a) 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 [~~abnormal~~] 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:

(i) Refer the patient out to a higher level of care; or

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

7. [6.] 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 3. Use of transmucosal buprenorphine mono-product or buprenorphine combined with naloxone for treatment of opioid use disorder in an emergency situation or inpatient setting.~~

~~(1) In an emergency, including in a hospital emergency department or similar outpatient urgent care setting, or in an inpatient setting, licensees may offer and initiate buprenorphine treatment to patients who present with opioid use disorder, without meeting the requirements established in Sections 1 and 2 of this administrative regulation and to the extent permitted by federal law, if:~~

~~(a) The licensee has determined that the use of buprenorphine mono-product or buprenorphine combined with naloxone will not result in a harmful interaction with other medications or substances in the patient's system, including benzodiazepines, sedative hypnotics, carisoprodol, or tramadol;~~

~~(b) The licensee obtains and documents written informed consent from the patient specific to risks and benefits of buprenorphine treatment; and~~

~~(c) The licensee provides the patient with written instructions and contact information for appropriate follow up care, including bridge provider services, residential treatment providers, and outpatient treatment providers.~~

~~(2) The licensee shall initiate buprenorphine treatment under an observed induction protocol with an initial dose not to exceed the dose equivalency of four (4) milligrams buprenorphine generic tablet, which may be followed by subsequent doses, up to a maximum of twenty four (24) milligrams buprenorphine generic tablet, if withdrawal persists and is not improving.~~]

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 [~~PEP20-02-01-006~~], Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021 [~~2020~~].

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 [~~PEP20-02-01-006~~] ", 2021 [~~2020~~].

(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 Web site at kbml.ky.gov.

Adopted:

12/12/2024

DATE

WILLIAM C. THORNBURY, M.D., PRESIDENT
KENTUCKY BOARD OF MEDICAL LICENSURE

PUBLIC HEARING AND PUBLIC 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 web site, 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.

CONTACT PERSON: Leanne K. Diakov, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502)764-2613, fax (502) 429-7118, email leanne.diakov@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 9:270
Contact Person: Leanne K. Diakov
Phone: (502) 764-2613
Email: leanne.diakov@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for prescribing, dispensing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone in the Commonwealth of Kentucky.

(b) The necessity of this administrative regulation: It is necessary to promulgate this regulation to establish acceptable and prevailing medical standards for prescribing, dispensing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone in the Commonwealth of Kentucky.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation acts specifically to establish requirements for Board licensees prescribing, dispensing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone in the Commonwealth of Kentucky.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation acts specifically to establish requirements for individual Board licensees prescribing, dispensing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone in the Commonwealth of Kentucky.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This administrative regulation amendment carves out exceptions for use of the products in certain clinical settings, deletes licensure and education requirements no longer required by federal law, and increases ease of access in various manners (such as no longer requiring pregnancy test before initiating treatment).

(b) The necessity of the amendment to this administrative regulation: It was necessary to amend the regulation in order to ensure that the regulation reflects updated and widely recognized acceptable and prevailing practice standards in an ever-developing area of medical practice and to increase patient access to quick and appropriate treatment.

(c) How the amendment conforms to the content of the authorizing statutes: This amended regulation acts specifically to further clarify and update the acceptable and prevailing medical practices for prescribing, dispensing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

(d) How the amendment will assist in the effective administration of the statutes: This amended regulation acts specifically to further clarify and update the acceptable and prevailing medical practices for prescribing, dispensing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This amendment will affect all physicians and physician assistants licensed in the Commonwealth of Kentucky who prescribe, dispense or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Physicians and physician assistants will be required to follow the professional standards for prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no cost associated with the requirements of this administrative regulation known to the Board.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Benefits to the physician and physician assistant include having updated professional standards for prescribing, dispensing or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone which will help curb the prescription drug epidemic in the Commonwealth of Kentucky and increase patient access to appropriate treatment.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: None.

(b) On a continuing basis: None.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: None.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase of fees or funding will be necessary.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish any fees nor does it directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals regulated by it.

FISCAL IMPACT STATEMENT

201 KAR 9:270
Contact Person: Leanne K. Diakov
Phone: (502) 764-2613
Email: leanne.diakov@ky.gov

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation: KRS 218A.205(3)(a) and (b), 311.565(1)(a) and 311.842(1)(b).

(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act: HB 1 (2013)

(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions: Kentucky Board of Medical Licensure

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:
   For the first year: None
   For subsequent years: None
2. Revenues:
   For the first year: None
   For subsequent years: None
3. Cost Savings:
   For the first year: None
   For subsequent years: None

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts): None

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:
   For the first year: None
   For subsequent years: None
2. Revenues:
   For the first year: None
   For subsequent years: None
3. Cost Savings:
   For the first year: None
   For subsequent years: None

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a): Physicians (MD/DOs) and Physician Assistants (PAs)

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year: None
For subsequent years: None

2. Revenues:
For the first year: None
For subsequent years: None

3. Cost Savings:
For the first year: None
For subsequent years: None

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a):

(a) Fiscal impact of this administrative regulation: The amendment of this administrative regulation will not have a major fiscal impact on state or local government or regulated entities.

(b) Methodology and resources used to reach this conclusion: N/A

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(13): The amendment of this administrative regulation will not have a major fiscal impact on state or local government or regulated entities.

(b) The methodology and resources used to reach this conclusion: N/A

FEDERAL MANDATE ANALYSIS COMPARISON

201 KAR 9:270
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(1) Federal statute or regulation constituting the federal mandate. N/A

(2) State compliance standards. See KRS 218A.205, 311.565 and .595/.597 and KRS 311.840 and .842.

(3) Minimum or uniform standards contained in the federal mandate. N/A

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This amended regulation matches federal law where applicable and provides more specific guidance that is absent from federal law.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Kentucky's Legislature mandates that this agency establish and enforce acceptable and prevailing practices related to the prescribing, dispensing and administering of controlled substances in the Commonwealth of Kentucky, a unique state interest. There is no corresponding federal mandate or interest.

Summary of Material Incorporated by Reference

The Substance Abuse-Mental Health Administration ("SAMHSA") Treatment Improvement Protocol ("TIP") (332 pages) is a federal source providing review of three (3) Food and Drug Administration ("FDA")-approved medications used to treat Opioid Use Disorder ("OUD"), including that most relevant to the proposed amended regulation: buprenorphine. It also recommends "best" strategies and services to support recovery for persons with OUD.

List of changes:

In May 2021, the TIP was revised to bring the content up to date and reflect more current data in regard to use of naltrexone and recent statistics, including:

- Updating statistics from SAMHSA, the Centers for Disease Control ("CDC"), and other health authorities on opioid-related deaths, overdoses, accidents, and hospitalizations.
- Clarifying whether references to naltrexone refer to the oral formulation or the extended-release injectable formulation.
- Supporting induction onto extended-release naltrexone of people with positive urine tests for opioids so long as they pass the naloxone challenge.
- Clarifying that naltrexone can result in decreased opioid cravings.