BOARDS AND COMMISSIONS
Kentucky Board of Medical Licensure
(Amendment)

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

RELATES TO: KRS 218A.205, 311.530-311.620, 311.990, 311.840-311.862
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 [~~physicians practicing in Kentucky~~] who prescribes, [~~prescribe or dispense~~] dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

Section 1. Minimum Qualifications for Prescribing, [~~or~~] Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. Except as provided in Section 3 of this administrative regulation, a licensee [~~licensed physician~~] shall not prescribe, [~~or~~] dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone unless that licensee [~~physician~~] possesses the minimum qualifications established in this section.

(1) The licensee [~~physician~~] 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.

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

(a) The prescribing licensee [~~physician~~] shall be a DEA-licensed prescriber of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone and shall have 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 [~~physician~~] 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 [~~physician~~] shall not report the prescribing, [~~or~~] dispensing, or administering [~~of~~] 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 2. Professional Standards for Prescribing, [or] 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, [or] 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, [or] 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;

(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)(a) Except as provided in paragraph (b) of this section, Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall not be prescribed, [or] dispensed, or administered to a patient who is also being prescribed 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, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry.

(b) A licensee [physician] may prescribe, [or] 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 [licensed physician] who prescribes, [or] 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, [or] dispensing, or administering licensee [physician] 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. Screening 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, [~~or~~] dispensing, or administering licensee [~~physician~~] shall review and incorporate the information from the records into the evaluation and treatment of the patient.

b. If the prescribing, [~~or~~] dispensing, or administering licensee [~~physician~~] is unable, despite best efforts, to obtain the patient's prior medical records, the licensee [~~physician~~] 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 [~~physician~~] shall require that the patient submit to a pregnancy test and, if pregnant, the licensee [~~physician~~] shall provide counseling as to the risk of neonatal abstinence syndrome which shall be consistent with current SAMHSA guidance.

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 [~~physician~~] who prescribes, [~~or~~] 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 [~~prescribing or dispensing physician~~] shall comply with the requirements of this paragraph.

1. The licensee [~~prescribing or dispensing physician~~] shall recommend to the patient an in-office observed induction protocol.

a. Except as provided in clause b. of this subparagraph, the licensee [~~prescribing or dispensing physician~~] shall supervise the in-office observed induction protocol.

b. If an in-office observed induction does not occur, the licensee [~~prescribing or dispensing physician~~] shall appropriately record the circumstances in the patient chart.

2. The licensee [~~prescribing or dispensing physician~~] shall document the presence 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 [~~prescribing or dispensing physician~~] 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 [~~prescribing or dispensing physician~~] shall:

1. Document that fact;

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

3. 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 induction of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, the licensee [~~prescribing or dispensing physician~~] shall meet the requirements established in this paragraph.

1. If the licensee [~~physician~~] prescribes, [~~or~~] dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone medication, the licensee [~~physician~~] 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 [~~physician~~] shall prescribe, [~~or~~] 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;

c. Except as provided in subclauses (i) through (iv) of this clause, is to be taken no more frequently than 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 [~~physician~~] visit, which shall be scheduled as required by subparagraph 3. of this paragraph.

3.a. The licensee [~~prescribing or dispensing physician~~] shall ensure that the patient is seen:

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

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

b. (i) If the patient demonstrates objective signs of positive treatment progress, the licensee [~~prescribing or dispensing physician~~] 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 [~~prescribing or dispensing physician~~] may require that the patient be seen only by the licensee [~~prescribing or dispensing physician~~] at least once every three (3) months.

(iii) The licensee [~~prescribing or dispensing physician~~] 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 [~~prescribing or dispensing physician~~] 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 [~~prescribing or dispensing physician~~] 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 [~~prescribing or dispensing physician~~] shall obtain KASPER reports to help guide the treatment plan.

a. If the KASPER indicates any abnormal findings, the licensee [~~prescribing or dispensing physician~~] 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 [~~prescribing or dispensing physician~~] is not 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, then the licensee [~~prescribing or dispensing physician~~] shall obtain a consultation 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 psychiatry 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.

d. The licensee [~~prescribing or dispensing physician~~] 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 [~~prescribing or dispensing physician~~] shall evaluate for and document the medical necessity for continued treatment at the established dose.

f. The licensee [~~prescribing or dispensing physician~~] 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 [~~prescribing or dispensing physician~~] shall resume the early treatment testing schedule, in conjunction with an adapted or intensified treatment plan.

(i) Each drug screen shall at a minimum screen for buprenorphine, methadone, opioids, THC, benzodiazepines, amphetamines, and cocaine.

(ii) If a drug screen indicates any abnormal findings, the licensee [~~prescribing or dispensing physician~~] 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, a consultation with a specialist, or an alternative treatment.

6. The licensee [~~prescribing or dispensing physician~~] 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 [~~physicians~~] 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 [~~physician~~] 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 [~~physician~~] obtains and documents written informed consent from the patient specific to risks and benefits of buprenorphine treatment; and

(c) The licensee [~~physician~~] 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 [~~physician~~] 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 [~~physician~~] prescribing, [~~or~~] 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 [~~physician~~] is conforming to professional standards for prescribing, [~~or~~] dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone and other relevant professional standards.

(2) If a licensee [~~physician~~] is unable to conform to professional standards for prescribing, [~~or~~] 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 [~~physician's~~] control, or the licensee [~~physician~~] 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 [~~physician~~] shall document those circumstances in the patient's record and only prescribe, [~~or~~] dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone to the patient if the

patient record appropriately justifies the prescribing, [~~or~~] dispensing, or administering of Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone under the circumstances and in accordance with SAMHSA guidelines.

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 [~~licensed physician~~] to sanctions authorized by KRS 311.595 and KRS 311.850.

SANDRA R. SHUFFETT, PRESIDENT

APPROVED BY AGENCY: October 14, 2020

FILED WITH LRC: October 14, 2020 at 10:52 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on December 21, 2020, at 9:30 a.m., at the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by 5 workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. This hearing is open to the public. Any person who wishes to be heard 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 the proposed administrative regulation. Written comments shall be accepted through December 31, 2020. 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) 429-7943, fax (502) 429-7118, email Leanne.Diakov@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Leanne K. Diakov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for prescribing or dispensing 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 or dispensing 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 the requirements for Board licensees prescribing or dispensing 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 the re-

quirements for individual Board licensees prescribing or dispensing 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: During the 2020 regular legislative session, the General Assembly amended the physician assistant statutes in order to allow that they may prescribe and administer controlled substances, including Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, and require that the Board adopt regulation setting forth prescribing standards for them. This administrative regulation amendment is necessary in order to hold physician assistants who prescribe or administer buprenorphine products accountable to the same standards as physicians.

(b) The necessity of the amendment to this administrative regulation: It is necessary to amend the administrative regulation in order to hold physician assistants who prescribe or administer buprenorphine products accountable to the same standards as physicians.

(c) How the amendment conforms to the content of the authorizing statutes: During the 2020 regular legislative session, the General Assembly amended the physician assistant statutes in order to allow that they may prescribe and administer controlled substances, including Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, and require that the Board adopt regulation setting forth prescribing standards for them. This administrative regulation amendment is necessary in order to hold physician assistants who prescribe or administer buprenorphine products accountable to the same standards as physicians.

(d) How the amendment will assist in the effective administration of the statues: During the 2020 regular legislative session, the General Assembly amended the physician assistant statutes in order to allow that they may prescribe and administer controlled substances, including Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, and require that the Board adopt regulation setting forth prescribing standards for them. This administrative regulation amendment is necessary in order to hold physician assistants who prescribe or administer buprenorphine products accountable to the same standards as physicians.

(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 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 physicians assistants will be required to follow the same 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 physicians and physician assistants include having consistent professional standards for prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone; benefits to the agency and the Commonwealth of Kentucky include curbing of the prescription drug epidemic and increasing patient access to appropriate treatment.

(5) Provide an estimate of how much it will cost 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 established any fees or directly or indirectly increased 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 NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Medical Licensure will be impacted by this administrative regulation.

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

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None.

(c) How much will it cost to administer this program for the first year? None.

(d) How much will it cost to administer this program for subsequent years? None.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: