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

RELATES TO: KRS 311.530-311.620, 311.990

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. This administrative regulation establishes the professional standards for physicians practicing in Kentucky who prescribe or dispense Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone.

Section 1. Minimum Qualifications for Prescribing or Dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. A licensed physician shall not prescribe or dispense Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone unless that physician possesses the minimum qualifications established in this section. (1) The 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 dependence in the Commonwealth of Kentucky.

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

(a) The prescribing 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.

(3) The 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 physician shall not report the prescribing or dispensing of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for medically-supervised withdrawal or as maintenance treatment for a patient diagnosed with opioid dependence into the Kentucky Health Information Exchange unless otherwise required by law.

Section 2. Professional Standards for Prescribing or Dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for Medically-Supervised Withdrawal or the Treatment of Opioid Dependency. (1)(a) Except as provided in paragraph (b) of this subsection, Buprenorphine-Mono-

Product or Buprenorphine-Combined-with-Naloxone shall only be prescribed or dispensed for medically-supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid dependence.

(b) Transdermal delivery of Buprenorphine-Mono-Product may be used for treatment of pain.

(2) Buprenorphine-Mono-Product shall not be prescribed or dispensed, except:

(a) To a pregnant patient;

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

(c) As an injectable treatment in a physician's office or other healthcare facility.

(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 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 Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry.

(b) A physician may prescribe or dispense 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) Each licensed physician who prescribes or dispenses Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for medically-supervised withdrawal or for the treatment of Opioid dependence shall fully comply with the professional standards established in this subsection.

(a) Prior to initiating treatment, the prescribing or dispensing 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 physical examination of the patient;

f. The patient's injection use history, which shall include screening for HIV and hepatitis serology; and

g. 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 physician shall review and incorporate the information from the records into the evaluation and treatment of the patient.

b. If the prescribing or dispensing physician is unable, despite best efforts, to obtain the patient's prior medical records, the 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) 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 physician shall require that the patient first submit to a pregnancy test and the physician shall provide counseling as to the risk of neonatal abstinence syndrome which shall be consistent with patient education material on neonatal abstinence syndrome from the American Congress of Obstetricians and Gynecologists, American Academy of Pediatrics, American Society of Addiction Medicine (ASAM) and the Kentucky Department for Public Health, and offer means to prevent pregnancy.

2.a. A physician shall not prescribe or dispense Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to a patient who is pregnant or breastfeeding unless the prescribing physician first obtains and documents consultation with another physician for an opinion as to whether 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 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 who is also qualified to prescribe buprenorphine.

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

1. The 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 prescribing or dispensing physician shall conduct the in-office observed induction protocol.

b. If an in-office observed induction does not occur, the prescribing or dispensing physician shall appropriately record the circumstances in the patient chart and shall implement a SAMHSA-recognized or ASAM-recognized home-based induction protocol.

2. The 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 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 is not improving; 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, the 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 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 prescribing or dispensing physician shall meet the requirements established in this paragraph.

1. If the physician prescribes or dispenses Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone medication, the 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 physician shall prescribe or dispense 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. Is to be taken no more frequently than once daily; and

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

3.a. The prescribing or dispensing physician shall ensure that the patient is seen by the physician:

(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 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 dependence 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 prescribing or dispensing physician may require that the patient be seen only by the prescribing or dispensing physician at least once every three (3) months.

(iii) The 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 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. Every three (3) months after initiation of treatment, the 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 prescribing or dispensing physician shall obtain KASPER reports to help guide the treatment plan.

a. If the KASPER indicates any abnormal findings, the 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 or frequency of visits, increased 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 prescribing or dispensing physician is not 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, then the prescribing or dispensing physician shall refer the patient for consultation by 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 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 prescribing or dispensing physician shall evaluate for and document the medical necessity for continued treatment at the established dose.

f. The prescribing or dispensing physician shall obtain at least eight (8) drug screens from the patient within each twelve (12) month period of treatment in order to help guide the treatment plan. For patients who have demonstrated objective signs of positive treatment progress for at least two (2) years from the date of initiation of treatment, including documented evidence that the patient has been compliant with the treatment plan and all treatment directives, the prescribing or dispensing physician shall obtain at least six (6) drug screens from the patient within each twelve (12) month period of treatment in order to help guide the treatment plan.

(i) At least two (2) of the drug screens shall be random and shall be coupled with a pill count.

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

(iii) If a drug screen indicates any abnormal findings, the 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.

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

6. The prescribing or dispensing physician shall document a plan for handling any lost or stolen medication, which:

a. Shall not provide for the automatic replacement of medication prior to the specified interval date; and

b. If the prescribing or dispensing physician determines that it is necessary to minimize improper or illegal diversion of medications under the circumstances, shall require the patient to first report the lost or stolen medications to police or other law enforcement agencies.

Section 3. Violations. Failure to comply with or a violation of the professional standards established in Section 2 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 311.595(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 licensed physician to sanctions authorized by KRS 311.595. (41 Ky.R. 1257; Am. 1670; 1975; eff. 4-3-2015; 42 Ky.R. 1907; eff. 6-3-16.)